UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)	· .
This Document Relates to:))	MDL No. 1:13-md-2419-FDS
Bland, et al. v. Ameridose, LLC, et al. 1:13-cv-11881-FDS)	

PROPOSED SECOND AMENDED COMPLAINT

The Plaintiffs, Carolyn and Leon Bland, for their cause of action against the defendants respectfully state to the Court as follows:

INTRODUCTION

- 1. This lawsuit arises as a result of a widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. Over 700 people have been diagnosed with meningitis and/or fungal infections.
- 2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control ("CDC") have identified fungus present in several separate lots of preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as "MPA"), that was compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.
- 3. Multiple vials of steroids compounded at NECC have been recalled but the recall was too late for Plaintiff Carolyn Bland and for many others who have suffered serious and at times catastrophic injuries.

- 4. During the period June through August 2012, Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Neurosurgical") purchased approximately two thousand five hundred (2,500) 80 mg. vials of MPA from NECC and then sold and administered the MPA to patients including Carolyn Bland.
- 5. On September 11, 2012, Carolyn Bland received a lumbar epidural steroid injection ("ESI") at Saint Thomas Neurosurgical. During that procedure the anesthesiologist injected 80 mg. of MPA into Carolyn Bland's lower back at L4-5.
- 6. Carolyn Bland's September 11, 2012 injection came from one or more contaminated lots of MPA that were purchased from NECC. The contaminated lots were subsequently recalled by NECC.
- 7. Carolyn Bland's September 11, 2012 injection of MPA caused her fungal meningitis.

PARTIES

- 8. Plaintiff Carolyn Bland is a citizen and resident of the Commonwealth of Kentucky and resides at 1160 Old Canton Pike, Cadiz, Kentucky 42211.
- 9. Plaintiff Leon Bland is a citizen and resident of the Commonwealth of Kentucky and resides at 1160 Old Canton Pike, Cadiz, Kentucky 42211.
- 10. Plaintiffs, Carolyn Bland and Leon Bland, are and, at all times relevant, were husband and wife.
- 11. Defendant Ameridose, LLC ("Ameridose") is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581.

The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

- 12. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director of MSM. Barry Cadden is the Treasurer and a Director of MSM. Gregory Conigliaro is the Secretary and a Director of MSM. MSM's registered agent is Gregory Conigliaro.
- 13. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 697 Waverly Street, Framingham, Massachusetts 01702. Douglas Conigliaro is the President and a Director, Barry Cadden is the Treasurer and a Director, Gregory Conigliaro is the Secretary and a Director and Lisa Conigliaro Cadden is a Director. MSMSW's registered agent is Gregory Conigliaro.
- 14. Defendant GDC Properties Management, LLC ("GDC"), is a Massachusetts limited liability company organized and domesticated under the laws of the Commonwealth of Massachusetts with its principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.
- 15. Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation organized and domesticated under the laws of the State of Oklahoma with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. Thomas C. Kupiec is the Chief Executive Officer and registered agent of ARL.

- 16. Defendant Barry J. Cadden ("Barry Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Barry Cadden is the President of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record. Barry Cadden is a founder and Manager of Ameridose and was involved in Ameridose's day to day operations. Barry Cadden is the Treasurer and Director of MSM and MSMSW.
- 17. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual residing at 1 Mountain View Drive, Framingham, Massachusetts 01701 and a citizen and resident of the Commonwealth of Massachusetts. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw day to day operations, and regularly appeared in the NECC facility. Gregory Conigliaro is the founder and a Manager of Ameridose and involved in Ameridose's day to day operations. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.
- 18. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual residing at 13 Manchester Drive, Wrentham, Massachusetts 02093 and a citizen and resident of the Commonwealth of Massachusetts. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day to day operations of NECC.
- 19. Defendant Douglas Conigliaro ("Douglas Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026 and a citizen and resident of the Commonwealth

of Massachusetts. Douglas Conigliaro is the President and Director of MSM and MSMSW. Douglas Conigliaro, upon information and belief, is involved in the day to day operations of NECC, Ameridose, MSM, and MSMSW.

- 20. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual residing at 15 Hale Drive, Dedham, Massachusetts 02026, and a citizen and resident of the Commonwealth of Massachusetts and is a Director of NECC.
- 21. Defendant Glenn A. Chin ("Glenn Chin") is an individual residing at 173 Mechanic Street, Canton, Massachusetts 02021 and a citizen and resident of the Commonwealth of Massachusetts. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glen Chin, upon information and belief, compounded drugs at NECC.
- 22. Defendant Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Neurosurgical") is a Tennessee for profit limited liability Company organized and domesticated under the laws of the State of Tennessee. Saint Thomas Neurosurgical's principal place of business is located on the 9th floor of the Medical Plaza East office building on the Saint Thomas Hospital campus at 4230 Harding Pike in Nashville, Davidson County, Tennessee 37205. Saint Thomas Neurosurgical's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.
- 23. Defendant Howell Allen Clinic A Professional Corporation, ("Howell Allen Clinic") is a Tennessee professional corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business in Nashville, Davidson County, Tennessee. Howell Allen Clinic's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

- 24. Defendant John Culclasure, M.D. ("Dr. Culclasure") is an individual residing at 1510 Demonbreun Street, Unit 1208, Nashville, Tennessee 37203 and a citizen and resident of the State of Tennessee. During all relevant times, John Culclasure was an employee of the Howell Allen Clinic and the Medical Director of Saint Thomas Neurosurgical. John Culclasure is a medical doctor and practices in the specialty of anesthesiology. John Culclasure was involved in the day to day operations at Saint Thomas Neurosurgical.
- 25. Defendant Debra Schamberg, R.N. ("Ms. Schamberg") is an individual residing at 2644 Mossdale Drive, Nashville, Tennessee 37217 and a citizen and resident of the State of Tennessee. During all relevant times, Debra Schamberg was an employee of Howell Allen Clinic and the Facilities Director of Saint Thomas Neurosurgical. Ms. Schamberg is a registered nurse and was involved in the day to day operations at Saint Thomas Neurosurgical.
- 26. Defendant Saint Thomas West Hospital is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business located on the Saint Thomas West Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas West Hospital was formerly known as St. Thomas Hospital. Saint Thomas West Hospital's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205. Hereinafter, Saint Thomas West Hospital shall be referred to as "St. Thomas Hospital."
- 27. At all times while providing treatment to Carolyn Bland at Saint Thomas Neurosurgical, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of St. Thomas Hospital and were acting within the course and scope of their employment, agency, or apparent agency with St. Thomas Hospital.

- 28. Pursuant to the doctrine of respondent superior, St. Thomas Hospital is vicariously liable for any negligent acts and omissions of their employees, agents, or representatives committed in the course and scope of their employment or agency while treating Carolyn Bland.
- 29. Defendant Saint Thomas Network is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business located on the St. Thomas Hospital campus at 4220 Harding Pike in Nashville, Davidson County, Tennessee. Saint Thomas Network's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205.
- 30. Defendant Saint Thomas Network was formerly known as Saint Thomas Health Services.
 - 31. Saint Thomas Network is a successor of Saint Thomas Health Services.
- 32. Saint Thomas Network, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.
- 33. Saint Thomas Network, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.
- 34. Defendant Saint Thomas Health is a Tennessee non-profit corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business in Nashville, Davidson County, Tennessee. Saint Thomas Health's registered agent for service of process is E. Berry Holt III, Suite 800, 102 Woodmont Boulevard, Nashville, Tennessee 37205.
- 35. Defendant Saint Thomas Health was formerly known as Saint Thomas Health Services.
 - 36. Saint Thomas Health is a successor of Saint Thomas Health Services.

- 37. Saint Thomas Health, as the successor of Saint Thomas Health Services, is a manager of Defendant Saint Thomas Neurosurgical.
- 38. Saint Thomas Health, as the successor of Saint Thomas Health Services, is an owner and/or member of Defendant Saint Thomas Neurosurgical.
- 39. Defendants Saint Thomas Network and Saint Thomas Health are hereinafter referred to collectively as "Saint Thomas."
- 40. At the time of the events described herein, Defendants Saint Thomas and Howell Allen Clinic acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.
- 41. The individuals and entities described in paragraphs 11-21 are sometimes collectively referred to as the "NECC Related Defendants."
- 42. The individuals and entities described in paragraphs 22-39 are sometimes collectively referred to as the "Tennessee Defendants."

JURISDICTION AND VENUE

- 43. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because as described herein each claim asserted herein is related to a case under title 11.
- 44. This case is related to the NECC Bankruptcy because the outcome of the proceeding certainly could have some effect on the bankruptcy estate.
- 45. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case no. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

- 46. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. Some if not all of the aforementioned individuals are insureds under NECC's insurance policies.
- 47. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each of the NECC Related Defendants.
- 48. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.
- 49. The Bankruptcy Court for the District of Massachusetts has not yet established a deadline for the filing of claims against NECC's bankruptcy estate in In re: New England Compounding Pharmacy, Inc.
- 50. By letter dated October 16, 2012, Saint Thomas Neurosurgical provided NECC with written notice of its intent to assert claims for breach of warranty and other remedies against NECC. In addition, Saint Thomas Neurosurgical and Howell Allen Clinic have actively represented themselves to the Bankruptcy Court for the District of Massachusetts as creditors of

NECC who have a stake in NECC's bankruptcy proceeding as a result of Plaintiffs' claims and the claims of those similarly situated. Saint Thomas Neurosurgical and Howell Allen Clinic objected to the Trustee's motion to establish a deadline for the filing of claims in Case no. 12:19882 HJB; they argued that the proposed deadline could prevent them from filing an accurate and comprehensive account of their contribution and indemnity claims against NECC. On July 24, 2013, during oral arguments on another motion filed in Case no. 12:19882 HJB, Saint Thomas Neurosurgical and Howell Allen Clinic characterized themselves to the Bankruptcy Court as creditors of NECC's bankruptcy estate possessed of indemnity and breach-of-warranty claims. In papers presented in response to that same motion, Saint Thomas Neurosurgical and Howell Allen Clinic insinuated that they intend to seek relief from the automatic stay for the purpose of pursuing indemnity claims against NECC.

- 51. Whatever contribution, indemnity, and breach-of-warranty claims Saint Thomas Neurosurgical and Howell Allen Clinic have against NECC are predicated on the contaminated methylprednisolone acetate purchased from NECC.
- 52. Upon information and belief, all of the Tennessee Defendants presently intend to seek, and will seek, relief from the stay in order to pursue contribution or indemnity claims against NECC for all or some portion of the damages sought by this Complaint. In addition or in the alternative, all of the Tennessee Defendants presently intend to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.
- 53. The Plaintiffs will file a claim against NECC in its bankruptcy proceeding for the injuries at issue in this Complaint.

- 54. By Order dated May 31, 2013, Judge Saylor, ruled that the New England Compounding Pharmacy, Inc. Multi District Litigation Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the defendants described in paragraphs 11-21.
- 55. In the alternative, this Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a)(1) because the amount in controversy of each individual Plaintiff's cause of action exceeds \$75,000.00, exclusive of interest and costs, and the citizenship of each Plaintiff is completely diverse from the citizenship of each Defendant.
- 56. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against the Tennessee Defendants pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.
- 57. Venue is proper and appropriate in the United States District Court for the Middle District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in Davidson County, Tennessee.
- 58. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing and/or selling or administering either directly, or indirectly steroids in the State of Tennessee from which they derived significant and regular income.

- 59. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Davidson County, Tennessee that have proximately caused the injuries that are the subject of this lawsuit.
- 60. The NECC Related Defendants described in paragraphs 11-21 are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF FACTS

Relevant background

- 61. NECC is an entity that has filed for bankruptcy and is protected by the automatic stay provisions of 11 U.S.C. § 362.
- 62. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to purchasers throughout the United States, including Tennessee.
- 63. Upon information and belief, NECC was a privately-held company that was owned and controlled by Barry Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Lisa Cadden.
- 64. Ameridose, GDC, MSM and MSMSW were affiliates of NECC at all relevant times.
- 65. At least until October 2012, Gregory Conigliaro was involved in co-managing day-to-day operations of NECC, MSM, MSMSW, Ameridose and GDC.

- 66. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.
- 67. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications including MPA at NECC.
- 68. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden was NECC's licensed Pharmacist Manager of Record.

 Upon information and belief, Barry Cadden compounded medications including MPA at NECC.
- 69. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."
- 70. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."
- 71. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.
- 72. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and

belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

- 73. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.
- 74. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including methylprednisolone acetate. One former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."
- 75. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.
- 76. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.
- 77. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.
- 78. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

Claims Against the NECC Related Defendants

79. NECC has a well-known history of adverse events relating to its operation as a compounding pharmacy. According to the Majority Memorandum for the November 14, 2012

Oversight and Investigations Subcommittee Hearing, NECC has been the subject of multiple complaints to and investigations by the FDA and the Massachusetts Board of Registration in Pharmacy ("MBP") over the past decade often focusing on unsterile conditions at NECC's facilities. For example, the FDA issued a Warning Letter to NECC in 2006. The FDA letter details numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. That warning letter has been available to the public on the FDA's website for years.

80. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of methylprednisolone acetate. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC knew or should have known of these findings. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to investigate those isolates and made no effort to identify those isolates. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn Chin, Ameridose, MSM and/or MSMSW and GDC failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound methylprednisolone acetate, and

Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

- 81. On September 26, 2012 in the wake of dozens of cases of fungal meningitis associated with NECC's injectable steroid MPA, state agents raided NECC's lab in a strip mall on Waverly Street in Framingham, Massachusetts.
- 82. NECC's few remaining employees were scrubbing the compounding areas with bleach. Despite this last-ditch effort, the "clean" rooms were filthy. A leaky boiler stood in a pool of stagnant, dirty water. The autoclaves used to sterilize the product were discolored, tarnished, and contained visible moisture. The air intake came from vents located about 100 feet from a mattress recycling facility that released copious amounts of dust and other contaminants into the air. The air vents in the "clean" rooms were covered with dirt and white fuzz. The metal shelf in the "clean" room used to prepare methylprednisolone acetate was covered in a reddish-brown, cloudy substance.
- 83. Investigators determined that NECC's internal records showed dozens of instances of bacterial and fungal contamination within the NECC facility over at least the past nine months. NECC ignored these test results. NECC never even attempted to get rid of these microbial contaminants.
- 84. Eighty-three out of three-hundred twenty one observed vials from one of three recalled lots of MPA contained a greenish-black substance visible to the human eye. Seventeen other vials contained a white filamentous material. All fifty out of fifty vials tested confirmed the presence of live microbes (whether fungal or bacterial). The CDC and FDA later confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate. This is the same fungus that the CDC confirmed was present in at least forty fungal meningitis cases.

- 85. Inspections of NECC's sister company Ameridose revealed similarly deplorable conditions, including countless instances of visible contamination of the hoods and rooms used to prepare drug products, insect infestations, birds flying through areas where purportedly sterile products were packaged and stored, and tubs being used to collect rain water that poured through the chronically leaky roof above the "clean" rooms. Ameridose, like NECC, persistently ignored and failed to investigate at least fifty-three instances of known microbiological contamination. Ameridose also hid adverse events associated with its products, failing to report them to the FDA as required by law and instead classifying these events as "patient responses" or "noncomplaints" and taking no action to address them.
- 86. The CDC determined that three lots of 80 mg/ml MPA produced by NECC between May 21 and September 26, 2012 were contaminated with potentially deadly pathogens.
- 87. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80 mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.
- 88. NECC identified Saint Thomas Neurosurgical in Nashville, Tennessee as one of the healthcare providers that received vials of methylprednisolone acetate that were part of the September 2012 recall.
- 89. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

- 90. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."
- 91. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists. Lisa Cadden also has voluntarily ceased her practice as a pharmacist. Upon information and belief, none of them have practiced as a pharmacist since voluntarily ceasing their practice.
- 92. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."
- 93. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).
- 94. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.
- 95. From May through August 2012, NECC sent several samples of its MPA to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

- 96. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.
- 97. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile." ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."
- 98. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.
- 99. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.
- 100. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were conducted in compliance with USP 71.
- 101. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

- 102. ARL was aware of the risks posed by compounding pharmacies, specifically including the risks posed by NECC's compounding practices.
- 103. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.
- 104. ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.
- 105. GDC which is an acronym for "Gregory D. Conigliaro" owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.
- 106. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.
- 107. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."
 - 108. GDC maintained a high degree of control over the premises leased by NECC.
- 109. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden, and Glenn Chin compounded, tested, marketed and/or distributed methylprednisolone acetate.
- 110. GDC and Gregory Conigliaro knew that NECC was compounding preservativefree methylprednisolone acetate at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

NECC and the risks of pharmacy compounding

- 111. The serious risks of pharmacy compounding were also the subject of considerable public discussion in the pharmacy community and the medical community before the subject fungal meningitis outbreak. The risks associated with compounded drugs have been known for years.
- 112. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that...follows appropriate measures to ensure that injectable products are free of contamination."
- 113. On March 24, 2005, *USA Today* published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs". That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.
- 114. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."
- 115. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded

products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

- 116. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.
- 117. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.

. . .

Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

118. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

The Fungal Meningitis Outbreak

119. In September 2012, health officials identified an outbreak of fungal meningitis. Investigators traced the outbreak to MPA compounded by NECC.

- 120. On September 18, 2012, a Vanderbilt University Medical Center clinician notified the Tennessee Department of Health of a patient with fungal meningitis who had received a series of epidural steroid injections at Saint Thomas Neurosurgical. On that same date, Dr. Marion Kainer of the Tennessee Department of Health, contacted St. Thomas Hospital and spoke with the hospital's Infection Preventionist, Candace Smith.
- 121. Dr. Kainer told personnel at St. Thomas Hospital that a sentinel event of concern had occurred in a patient who received epidural steroid injections at Saint Thomas Neurosurgical. She requested information from the hospital about the procedure, and she requested that the hospital commence an inspection of the Saint Thomas Neurosurgical clinic. She explained that the event required careful investigation, and she requested that the hospital watch for additional potential cases.
- 122. Two days later, on September 20, 2012, St. Thomas Hospital reported to the Tennessee Department of Health ("TDH") that two additional patients with meningitis and high levels of white blood cells of unknown cause reported to the hospital. Both of those patients had likewise received ESIs at Saint Thomas Neurosurgical. St. Thomas Hospital also reported that methylprednisolone acetate used in the ESIs was obtained from NECC.
- 123. On September 20, 2012, Saint Thomas Neurosurgical closed voluntarily, sequestered its supplies and ordered new supplies from other distributors.
- 124. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

- 125. According to the CDC, symptoms of meningitis include the following: new or worsening headache; fever; sensitivity to light; stiff neck; new weakness or numbness in any part of the body; slurred speech; and increased pain, redness or swelling at the injection site. Death may result from meningitis.
- 126. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg's Decision to Purchase MPA from NECC

- 127. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg are sometimes collectively referred to as the "Saint Thomas Neurosurgical defendants."
- 128. During all relevant times, Dr. Culclasure and Ms. Schamberg co-managed Saint Thomas Neurosurgical's day to day operations.
- 129. During all relevant times, Dr. Culclasure and Ms. Schamberg were directly involved and responsible for Saint Thomas Neurosurgical's decision to purchase MPA from NECC.
- 130. Saint Thomas Neurosurgical its agents and employees, Dr. Culclasure and Ms. Schamberg knew or should have known of the dangers of using compounded drugs and specifically products compounded by NECC. These defendants failed to undertake any appropriate due diligence to ascertain the safety and quality of NECC's products.

- 131. The only motivation for Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg to purchase steroids in bulk from NECC was price.
- 132. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg made the decision to purchase MPA in bulk from NECC because it was the cheapest steroid.
- 133. The Saint Thomas Neurosurgical defendants did not conduct appropriate due diligence or investigation into NECC before deciding to purchase and administer NECC compounded steroids to their patients. The Saint Thomas Neurosurgical defendants placed their own profits over patient safety.
- 134. NECC was not authorized to compound and sell MPA in bulk to Saint Thomas Neurosurgical.
- 135. NECC was only allowed to fill individual prescriptions for individual patients written by appropriately licensed healthcare providers.
- 136. Saint Thomas Neurosurgical did not use patient specific individual prescriptions when buying MPA from NECC in bulk.
- 137. Saint Thomas Neurosurgical could have purchased MPA for use in epidural steroid injections ("ESI") from a compounder other than NECC.
- 138. Saint Thomas Neurosurgical could have purchased MPA for use in ESI's from a pharmaceutical manufacturer, e.g. Pfizer.
- 139. From 2000 to the present the medication formulary for Saint Thomas Neurosurgical lists those steroids acceptable for use at Saint Thomas Neurosurgical and includes: Decadron, Depo-medrol, Solumedrol and Celestone Soluspan.

- 140. The Saint Thomas Neurosurgical formulary does not include generic methylprednisolone acetate ("MPA") or MPA from a compounding company as acceptable for use at Saint Thomas Neurosurgical.
- 141. The Saint Thomas Neurosurgical formulary does include and allow for the administration of methylprednisolone acetate manufactured by Pfizer under the name Depomedrol.
- 142. In late 2010, Saint Thomas Neurosurgical began purchasing MPA from Clint Pharmaceuticals.
- 143. The MPA that Saint Thomas Neurosurgical purchased from Clint Pharmaceuticals came from an FDA approved manufacturer.
- 144. Clint Pharmaceuticals represents that it has historically recommended that practitioners not use compounded steroids especially when FDA approved products are available. Saint Thomas Neurosurgical purchased MPA from Clint Pharmaceuticals at the price of \$6.49 per 80mg vial.
- 145. In May 2011, an NECC sales representative emailed Saint Thomas Neurosurgical's facility director, Ms. Schamberg, asking what price NECC would need to offer for MPA in order to gain Saint Thomas Neurosurgical's business. Ms. Schamberg replied that if NECC could get the price under \$6.50 per vial she would be willing to "talk" to NECC.
- 146. On June 9, 2011, Clint Pharmaceuticals increased the price to Saint Thomas Neurosurgical for MPA from \$6.49 to \$8.95 per vial, an increase of \$2.46 per vial.
- 147. Saint Thomas Neurosurgical was not willing to pay \$8.95 per vial of MPA from Clint Pharmaceuticals if it could be procured more cheaply from NECC.

- 148. On June 10, 2011, Ms. Schamberg on behalf of Saint Thomas Neurosurgical emailed an NECC sales representative indicating that if NECC would guarantee a price for MPA of \$6.50 per 80mg vial, Saint Thomas Neurosurgical would be willing to do business with NECC. (June 10, 2011 email from Ms. Schamberg attached as Exhibit A).
- 149. After NECC indicated its willingness to sell Saint Thomas Neurosurgical MPA for \$6.50 per 1mL 80mg vial, Ms. Schamberg obtained approval from Dr. Culclasure to begin ordering from NECC.
- 150. Both Ms. Schamberg and Dr. Culclasure approved the purchases of MPA from NECC.
- 151. Saint Thomas Neurosurgical placed its first order with NECC on or about June 10, 2011. That order consisted of 500 1mL 80 mg vials of MPA and 200 2mL 80 mg vials of MPA.
- 152. A copy of the Prescription Order Form referenced in the preceding paragraph reflecting Saint Thomas Neurosurgical's first order with NECC is attached as Exhibit B.
- 153. The June 2011 order form attached as Exhibit B did not contain any patient names despite the fact that the order form included a column for that information.
- 154. As evidenced by Dr. John Culclasure's name/signature on the June 2011 order form attached as Exhibit B, Dr. Culclasure was aware of and approved the purchase of MPA from NECC.
- 155. NECC sent invoices to Saint Thomas Neurosurgical evidencing five separate purchases by Saint Thomas Neurosurgical of five-hundred 80 mg. vials of MPA as reflected in invoices dated June 6, 2012, June 26, 2012, July 25, 2012, August 13, 2012 and August 31, 2012. (Invoices attached as Exhibit C).

- 156. NECC charged Saint Thomas Neurosurgical \$6.50 for each 80 mg. vial of MPA. (Exhibit C).
- 157. In early to mid-2012, an NECC representative informed Ms. Schamberg that NECC needed Saint Thomas Neurosurgical to submit a list of patients with each order in order to comply with Massachusetts Board of Pharmacy rules.
- 158. Ms. Schamberg told the NECC representative that she could not predict which patients would receive MPA. The NECC representative indicated that a list of previous patient names would suffice.
- 159. Saint Thomas Neurosurgical provided NECC with lists of patients' names (including Mickey Mouse) with its order(s) for MPA from NECC. Saint Thomas Neurosurgical provided those patient lists to NECC even though the patients on those lists did not necessarily receive MPA.
- 160. Plaintiffs attach as Exhibit D a list of patient names (redacted) submitted to NECC by Saint Thomas Neurosurgical showing the name "Mickey Mouse."
- 161. Defendants Dr. Culclasure, Ms. Schamberg and Saint Thomas Neurosurgical knew or should have known that sending a list of patient names to NECC including "Mickey Mouse" was inappropriate and unlawful. Such conduct evidenced an effort by Dr. Culclasure, Ms. Schamberg and Saint Thomas Neurosurgical to collude with NECC and was an effort to subvert Massachusetts Board of Pharmacy requirements.
- 162. By sending the list of patient names to NECC, Defendants Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg unlawfully conspired and acted in concert with NECC to violate Massachusetts Board of Pharmacy patient safety requirements thereby resulting in harm to Carolyn Bland and other patients who received NECC's MPA.

163. Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg knew of NECC's intent to use patient lists to circumvent Massachusetts Board of Pharmacy requirements.

Carolyn Bland is injected with MPA from NECC and develops fungal meningitis

- 164. In August 2012 Carolyn Bland saw Gregory Lanford, M.D. at the Howell Allen Clinic complaining of lower extremity numbness and low back pain. Dr. Lanford evaluated Carolyn Bland and recommended epidural steroid injections.
- 165. Howell Allen referred Carolyn Bland to Saint Thomas Neurosurgical for epidural steroid injections.
- 166. On September 11, 2012, Carolyn Bland received a lumbar epidural steroid injection at Saint Thomas Neurosurgical. During that procedure the anesthesiologist injected 80 mg. of MPA into Carolyn Bland's lower back at L4-5.
- 167. Carolyn Bland's September 11, 2012 injection came from one or more contaminated lots of MPA purchased from NECC. The contaminated lots were subsequently recalled by NECC.
- 168. Carolyn Bland's September 11, 2012 injection of MPA caused her fungal meningitis.
- 169. On or about September 20, 2012 someone from Saint Thomas Neurosurgical called Carolyn Bland to say that a doctor would not be available on September 21, 2012 to perform Carolyn Bland's second scheduled ESI.
- 170. No one on behalf of Saint Thomas Neurosurgical or the Howell Allen Clinic contacted Carolyn Bland on September 20, 2012 to inquire about troubling symptoms or to request that she come in for evaluation. No one on behalf of Saint Thomas Neurosurgical told her that Saint Thomas Neurosurgical had closed.

- 171. On September 21, 2012 someone from Saint Thomas Neurosurgical called Carolyn Bland and rescheduled her ESI to October 5, 2012.
- 172. No one on behalf of Saint Thomas Neurosurgical or the Howell Allen Clinic contacted Carolyn Bland on September 21, 2012 to inquire about troubling symptoms or to request that she come in for evaluation.
- 173. Between September 21, 2012 and September 27, 2012, no one on behalf of Saint Thomas Neurosurgical or the Howell Allen Clinic contacted Carolyn Bland to inquire about troubling symptoms or to request that she come in for evaluation.
- 174. On or about September 28, 2012, someone on behalf of Saint Thomas Neurosurgical or the Howell Allen Clinic called Carolyn Bland inquiring about how she was doing. There was no mention made of fungal meningitis.
- 175. On October 1, 2012 Carolyn Bland developed a headache, neck pain and back pain.
- 176. On October 3, 2012 Carolyn Bland presented to the St. Thomas Hospital emergency room. A lumbar puncture revealed an elevated white blood cell count.
- 177. Carolyn Bland was diagnosed with fungal meningitis and admitted to St. Thomas Hospital where she was treated with anti-fungal medication. Carolyn Bland remained a patient at St. Thomas Hospital until November 3, 2012.
- 178. The MPA injected into Carolyn Bland's lumbar spine came from one or more of the three recalled contaminated lots.
- 179. As a direct and proximate result of the contaminated epidural steroid injections, Carolyn Bland contracted fungal meningitis, became very ill and continues to suffer from the effects of fungal meningitis.

CAUSES OF ACTION

COUNT I CIVIL CONSPIRACY

- 180. All allegations above are incorporated herein by reference.
- 181. Defendants Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg acted in concert with NECC to accomplish the unlawful purpose of circumventing Massachusetts Board of Pharmacy patient safety requirements. Those Defendants accomplished that unlawful purpose via the unlawful means of using bogus patient lists to accompany orders of MPA. Those patient lists did not correspond with persons who actually received MPA, and the lists contained fictitious names such as "Mickey Mouse."
- 182. Defendants Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg were aware of NECC's intent to use such patient lists in order to subvert Massachusetts Board of Pharmacy requirements.
- 183. The concerted action of NECC, Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg resulted in harm to Carolyn Bland and other patients who received NECC's MPA.
- 184. Defendants Saint Thomas Neurosurgical, Dr. Culclasure and Ms. Schamberg are liable for the acts of their co-conspirator NECC.

COUNT II DUTY TO PREVENT FORESEEABLE HARM BY NECC (Against Tennessee Defendants)

- 185. All allegations above are incorporated herein by reference.
- 186. Carolyn Bland played no role in selecting the supplier of the MPA that the Defendant Saint Thomas Neurosurgical, through its agents and employees, injected into her

spine. Carolyn Bland relied exclusively upon Saint Thomas Neurosurgical, and its employees and agents, to make that selection.

- 187. Given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Saint Thomas Neurosurgical to purchase injectable steroids from NECC in bulk and without individual prescriptions.
- 188. Given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Saint Thomas Neurosurgical to conspire with NECC in the creation of false paper trails intended to hide NECC's wrongful and intentional conduct from regulators.
- 189. The Tennessee Defendants stood in a special relationship with Carolyn Bland. By virtue of that special relationship, the Tennessee Defendants owed a duty to protect their patients, including Carolyn Bland, from foreseeable harm caused by NECC's intentional conduct.
- 190. NECC engaged in numerous instances of intentional misconduct. That intentional misconduct included but is not limited to: (a) mass producing compounded medications and selling them in bulk in circumvention of the FDA system of regulating drug manufacturers; (b) providing false information to government regulators; (c) mass producing compounded medications and shipping those medications to Tennessee without patient specific prescriptions in violation of Massachusetts Board of Pharmacy Rules and Tenn. Code Ann. § 63-10-204(4); (d) enlisting the aid of its customers (including Saint Thomas Neurosurgical) in creating false paper trails designed to hide its misconduct from government regulators; and (e) mass producing purportedly sterile injectable drugs under filthy conditions in violation of regulations

promulgated by the Massachusetts Board of Registration in Pharmacy and found at 247 CMR 6.02(1).

- 191. The Tennessee Defendants breached their duty to their patients, including Carolyn Bland, by failing to protect them from the foreseeable harm caused by NECC's intentional conduct.
- 192. As a direct and proximate result of the Tennessee Defendants' breach of their duties, Carolyn Bland contracted fungal meningitis.
- 193. Because the Tennessee Defendants owed Carolyn Bland a duty to protect her from NECC's conduct, the Tennessee Defendants' fault cannot be reduced by any fault attributable to NECC. Accordingly, the Tennessee Defendants are jointly and severally liable for all harm caused by NECC's conduct.

COUNT III NEGLIGENCE (Against NECC Related Defendants)

- 194. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to Plaintiffs to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Plaintiff Carolyn Bland.
 - 195. Specifically, but without limitation:
 - a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiffs a duty to provide methylprednisolone acetate that was safe and free of contamination.
 - b. ARL owed Plaintiffs a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.

- 196. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to the Plaintiff. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.
- 197. Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test and distribute MPA so that it would not be contaminated with fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe compounded medications to reach the stream of commerce for use by Plaintiff.
- 198. Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiffs by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.
- 199. The negligence of Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin was a proximate cause of Plaintiffs' injuries.
- 200. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into her in September, 2012.

COUNT IV NEGLIGENCE PER SE (Against all NECC Related Defendants except ARL)

- 201. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin owed Plaintiffs a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.
- 202. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin breached the duties owed to Plaintiffs by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.
- 203. Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.
- 204. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Plaintiffs' injuries.

COUNT V NEGLIGENT SUPERVISION (Against NECC Related Defendants)

205. Defendants Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make

sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medication.

- 206. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:
 - a. The Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees.
 - b. Defendants also failed to monitor and supervise the testing of the compounded medications.
 - c. The Defendants were negligent in hiring, training, and supervising their employees.
- 207. The Defendants knew, or should have known, that their employee(s) or agent(s) did not follow proper procedures and knew or should have known of the risks created by failing to do so.
- 208. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including the Plaintiff, Carolyn Bland.
- 209. The aforementioned actions by Ameridose, MSM/MSMSW, GDC, ARL, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro and Glenn Chin were a proximate cause of Plaintiffs' injuries.

COUNT VI PUBLIC NUISANCE (Against Barry Cadden, Gregory Conigliaro and GDC)

210. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

- 211. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.
- 212. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.
- 213. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.
- 214. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.
- 215. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).
- 216. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC was a proximate cause of Plaintiffs' injuries.
- 217. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC has caused Carolyn Bland special injury in that Carolyn Bland has sustained injuries to her personal health.

COUNT VII PRODUCT LIABILITY CLAIMS

(Against Saint Thomas Neurosurgical and Howell Allen Clinic)

218. The MPA injected into Carolyn Bland's lumbar spine on September 11, 2012 was compounded by NECC.

- 219. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts In re: New England Compounding Pharmacy, Inc., case no. 12-19882-HJB.
- 220. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.
- 221. Plaintiffs could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.
- 222. Plaintiffs' claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).
 - 223. NECC has ceased operations.
 - 224. NECC is unable to pay its debts as they fall due.
 - 225. NECC is unable to pay its debts in the ordinary course of its business.
 - 226. NECC's liabilities exceed its assets.
 - 227. NECC is insolvent.
- 228. On July 24, 2013 The United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc. Case no. 12-19882-HJB ordered that with respect to certain claims, including those asserted by Plaintiffs in this lawsuit, NECC is presently insolvent and has been insolvent at all times since the petition date.
- 229. Saint Thomas Neurosurgical procured the MPA injected into Carolyn Bland's lumbar spine from NECC.
- 230. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same

condition at the time that Saint Thomas Neurosurgical and Howell Allen Clinic injected it into Carolyn Bland's lumbar spine on September 11, 2012.

- 231. Saint Thomas Neurosurgical and Howell Allen Clinic charged Carolyn Bland for epidural steroid injections administered to Carolyn Bland.
- 232. Saint Thomas Neurosurgical and Howell Allen Clinic acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Carolyn Bland.
- 233. Saint Thomas Neurosurgical and Howell Allen Clinic were engaged in the business of selling MPA compounded by NECC.
- 234. Accordingly, Saint Thomas Neurosurgical and Howell Allen Clinic are "sellers" as defined by Tenn. Code Ann. § 29-28-102(7).
- 235. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiffs Carolyn and Leon Bland to prosecute product liability claims against Saint Thomas Neurosurgical and Howell Allen Clinic as the seller of the MPA injected into Carolyn Bland's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.
- 236. Tenn. Code Ann. § 29-28-106(5) authorizes Plaintiffs Carolyn Bland and Leon Bland to prosecute product liability claims against Saint Thomas Neurosurgical and Howell Allen Clinic as the seller of the MPA injected into Carolyn Bland's lumbar spine because the compounder of the product, NECC, has been judicially declared insolvent.
- 237. The MPA that Saint Thomas Neurosurgical and Howell Allen Clinic injected into Carolyn Bland's lumbar spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

- 238. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).
- 239. The MPA sold and distributed by Saint Thomas Neurosurgical and Howell Allen Clinic was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Saint Thomas Neurosurgical and Howell Allen Clinic breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314 and 47-2-315, including its warranty of fitness for a particular purpose.
- 240. Saint Thomas Neurosurgical and Howell Allen Clinic are strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Carolyn Bland's lumbar spine.

COUNT VIII OTHER CLAIMS AGAINST SAINT THOMAS NEUROSURGICAL

- 241. Saint Thomas Neurosurgical's decision to select NECC as its supplier of purportedly sterile injectable steroids was negligent.
- 242. Saint Thomas Neurosurgical knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.
- 243. Saint Thomas Neurosurgical acting through its agents, employees and representatives, negligently and recklessly purchased contaminated MPA from NECC.
- 244. Saint Thomas Neurosurgical failed to conduct appropriate due diligence regarding NECC. Had they done so, any reasonable purchaser would have declined to purchase from NECC.

- 245. Saint Thomas Neurosurgical, acting though its physicians, nurses, managers, agents and employees, was negligent in its care and treatment of Carolyn Bland. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and drug procurement practices in this or similar communities and was a proximate cause of Carolyn Bland's injuries and damages. Specifically, Saint Thomas Neurosurgical was negligent and rendered substandard care in the following respects:
 - a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
 - b. failed to visit NECC's facilities before procuring spinal injection medicines from that company;
 - c. failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;
 - d. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;
 - e. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;
 - f. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;
 - g. failed to keep abreast of the dangers of sterile compounding;
 - h. purchased compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions;
 - i. failed to adequately supervise and train the physicians, nurses, agents and employees who ordered MPA from NECC;

- j. failed to follow its own formulary that would have prevented the use of MPA compounded by NECC in epidural steroid injections;
- k. failed to implement policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;
- 1. injected steroids into Carolyn Bland's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;
- m. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives; and
- n. failed to promptly notify Carolyn Bland that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt treatment of her potential fungal infection.
- 246. As a direct and proximate result of the negligent acts and omissions described above, Carolyn Bland suffered injuries and damages that would not have otherwise occurred.
- 247. The physicians, nurses, agents, employees and representatives who decided to procure MPA from NECC and who injected that steroid into Carolyn Bland's lumbar spine were employees or agents of Saint Thomas Neurosurgical, and they were acting within the course and scope of their employment or agency. Accordingly, Saint Thomas Neurosurgical is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

COUNT IX

CLAIMS AGAINST JOHN CULCLASURE, M.D. AND DEBRA SCHAMBERG, R.N.

248. Dr. Culclasure as Medical Director of Saint Thomas Neurosurgical and Ms. Schamberg as Facilities Director of Saint Thomas Neurosurgical made the decision to purchase MPA from NECC.

- 249. Dr. Culclasure and Ms. Schamberg were involved in co-managing the day to day operations at Saint Thomas Neurosurgical.
- 250. Dr. Culclasure and Ms. Schamberg were negligent in their selection of NECC as a supplier of MPA to Saint Thomas Neurosurgical.
- 251. Dr. Culclasure and Ms. Schamberg knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.
- 252. Dr. Culclasure and Ms. Schamberg failed to conduct appropriate due diligence regarding NECC. Had they done so, any reasonable purchaser would have declined to purchase from NECC.
- 253. Dr. Culclasure and Ms. Schamberg's decision to purchase MPA in bulk from NECC was based solely on price.
- 254. In making the decision to purchase compounded MPA from NECC, Dr. Culclasure and Ms. Schamberg failed to follow the medication formulary adopted by Saint Thomas Neurosurgical.
- 255. Defendants John Culclasure, M.D. and Debra Schamberg, R.N. were negligent in their care and treatment of Carolyn Bland. Such care and treatment fell below the recognized standard of acceptable professional practice for physicians and registered nurses in similar circumstances in this or similar communities and was a proximate cause of Carolyn Bland's injuries and damages. Specifically, Dr. Culclasure and Ms. Schamberg were negligent and rendered substandard care in the following respects:
 - a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

- b. failed to visit NECC's facilities before procuring spinal injection medicines from that company;
- c. failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;
- d. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;
- e. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;
- f. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;
- g. failed to keep abreast of the dangers of sterile compounding;
- h. failed to follow Saint Thomas Neurosurgical's own formulary that would have prevented the use of MPA compounded by NECC in epidural steroid injections;
- i. injected steroids into Carolyn Bland's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;
- j. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives;
- k. purchased compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions; and
- 1. submitted lists of previous patients' names (including Mickey Mouse) to NECC when ordering MPA even though such lists did not correspond with patients who actually received MPA.
- 256. As a direct and proximate result of the negligent acts and omissions described above, Carolyn Bland suffered injuries and damages that would not have otherwise occurred.

COUNT X OTHER CLAIMS AGAINST HOWELL ALLEN CLINIC

- 257. Howell Allen Clinic, acting through its physicians, nurses, agents, employees and representatives including John Culclasure and Debra Schamberg operated Saint Thomas Neurosurgical.
- 258. Howell Allen Clinic, acting through its physicians, nurses, agents, employees and representatives, was negligent in the manner in which it operated Saint Thomas Neurosurgical.
- 259. Howell Allen Clinic knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.
- 260. Howell Allen Clinic, acting though its physicians, nurses, agents, employees and representatives, was negligent in its care and treatment of Carolyn Bland. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and drug procurement practices in this or similar communities and was a proximate cause of Carolyn Bland's injuries and damages.
 - 261. Howell Allen Clinic was negligent in the following respects:
 - a. operated Saint Thomas Neurosurgical in a manner which facilitated the procurement of injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
 - b. failed to visit NECC's facilities before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;
 - c. failed to determine whether NECC had a history of recalling compounded medications before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from that company;

- d. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;
- e. failed to determine whether NECC had a history of product liability suits before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;
- f. failed to keep abreast of the dangers of sterile compounding while operating Saint Thomas Neurosurgical;
- g. failed to operate Saint Thomas Neurosurgical with reasonable and due care, including a complete failure to supervise its drug procurement practices reasonably;
- h. failed to supervise Saint Thomas Neurosurgical adequately;
- i. allowed Saint Thomas Neurosurgical to procure compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions;
- j. failed to adequately supervise and train the physicians, nurses, agents and employees who ordered MPA from NECC;
- k. failed to implement or enforce policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;
- 1. facilitated or permitted the injection of steroids into Carolyn Bland's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens; and
- m. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives; and
- n. failed to promptly notify Carolyn Bland that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt treatment of her potential fungal infection.
- 262. As a direct and proximate result of the negligent acts and omissions described above, Carolyn Bland suffered injuries and damages that would not have otherwise occurred.

- 263. The physicians, nurses, agents, employees and representatives who decided to procure MPA from NECC and who injected that steroid into Carolyn Bland's lumbar spine were employees or agents of Howell Allen Clinic, and they were acting within the course and scope of their employment or agency. Accordingly, Howell Allen Clinic is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.
- 264. Howell Allen Clinic represented to patients that Saint Thomas Neurosurgical is part of Howell Allen Clinic. Saint Thomas Neurosurgical, its physicians, nurses and employees were the actual or apparent agents of Howell Allen Clinic. Howell Allen Clinic is liable for the conduct of Saint Thomas Neurosurgical, its physicians, nurses, employees and representatives under the doctrine of *respondeat superior* and basic principles of agency both express and apparent agency. In addition, Saint Thomas Neurosurgical is the alter ego of Howell Allen Clinic.
- 265. Howell Allen Clinic operated Saint Thomas Neurosurgical and failed to maintain an arms-length relationship with that entity. Through its operation of Saint Thomas Neurosurgical, Howell Allen Clinic dominated and controlled Saint Thomas Neurosurgical, while employing its Medical Director and its Facility Director, such that Saint Thomas Neurosurgical functioned as an instrumentality of Howell Allen Clinic.

COUNT XI CLAIMS AGAINST ST. THOMAS HOSPITAL

266. Saint Thomas Neurosurgical, its physicians, nurses and employees were the actual or apparent agents of St. Thomas Hospital. St. Thomas Hospital is liable for the conduct of Saint Thomas Neurosurgical, its physicians, nurses, employees and representatives under the doctrine of respondeat superior and basic principles of agency.

267. Saint Thomas Neurosurgical is the actual, ostensible, and apparent agent of St. Thomas Hospital. Saint Thomas Neurosurgical is the agent of St. Thomas Hospital because Saint Thomas Neurosurgical shares a common name with St. Thomas Hospital. In addition, Saint Thomas Neurosurgical's clinic is located in the Saint Thomas Medical Plaza office building located on the St. Thomas Hospital campus. Plaintiff Carolyn Bland relied on the reputation of St. Thomas Hospital when accepting medical care at Saint Thomas Neurosurgical. St. Thomas Hospital did not give notice to patients of Saint Thomas Neurosurgical that it was not the provider of care or that the care provided by Saint Thomas Neurosurgical was not subject to the control and supervision of St. Thomas Hospital. In addition, once the fungal meningitis outbreak occurred, Saint Thomas Neurosurgical instructed many patients to report to the St. Thomas Hospital emergency room for evaluation and treatment.

$\begin{array}{c} \text{COUNT XII} \\ \text{CLAIMS AGAINST SAINT THOMAS}^1 \end{array}$

- 268. Saint Thomas and Howell Allen Clinic acted in concert to operate jointly the Defendant Saint Thomas Neurosurgical.
- 269. Saint Thomas and Howell Allen Clinic were negligent in the manner in which they operated Saint Thomas Neurosurgical.
- 270. Saint Thomas and Howell Allen Clinic knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.
 - 271. Saint Thomas was negligent in the following respects:
 - a. operated Saint Thomas Neurosurgical in a manner which facilitated the procurement of injectable steroids from NECC, for

¹ As noted in paragraph 39 above, Defendants Saint Thomas Network and Saint Thomas Health are collectively referred to as "Saint Thomas."

- the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;
- b. failed to visit NECC's facilities before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;
- c. failed to determine whether NECC had a history of recalling compounded medications before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from that company;
- d. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;
- e. failed to determine whether NECC had a history of product liability suits before permitting its agent Saint Thomas Neurosurgical to procure spinal injection medicines from NECC;
- f. failed to keep abreast of the dangers of sterile compounding while operating Saint Thomas Neurosurgical;
- g. failed to operate Saint Thomas Neurosurgical with reasonable and due care, including a complete failure to supervise its drug procurement practices reasonably;
- h. failed to supervise Saint Thomas Neurosurgical adequately;
- i. failed to exercise due and reasonable care in conducting Saint Thomas Neurosurgical's financial and contracting operations;
- j. allowed Saint Thomas Neurosurgical to procure compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions;
- k. failed to adequately supervise and train the physicians, nurses, agents and employees who ordered MPA from NECC;
- 1. failed to implement or enforce policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

- m. facilitated or permitted the injection of steroids into Carolyn Bland's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;
- n. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives; and
- o. failed to promptly notify Carolyn Bland that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt treatment of her fungal infection.
- 272. The person or persons who decided to procure MPA from NECC were employees or agents of Saint Thomas and were acting within the course and scope of their employment or agency. Accordingly, Saint Thomas is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of respondeat superior.
- 273. Saint Thomas Neurosurgical is the actual, ostensible, and apparent agent of Saint Thomas. Therefore, in addition to Saint Thomas being directly liable for its own conduct, it is also liable for the conduct of its agent, Saint Thomas Neurosurgical, under the doctrine of respondent superior and under basic principles of agency.
- 274. Saint Thomas Neurosurgical is the agent of Saint Thomas because Saint Thomas Neurosurgical shares Saint Thomas' name, is located on Saint Thomas' campus and is operated in part by Saint Thomas. Saint Thomas handles Saint Thomas Neurosurgical's contracting and finances. Moreover, once the fungal meningitis outbreak occurred, Saint Thomas Neurosurgical instructed many patients to report to the St. Thomas Hospital emergency room for evaluation and treatment.
- 275. Saint Thomas Neurosurgical and Saint Thomas failed to maintain an arms-length relationship. Saint Thomas Neurosurgical is the alter ego of Saint Thomas.

276. Upon information and belief, Saint Thomas Neurosurgical is grossly undercapitalized and unable to meet its obligations to the victims of the fungal meningitis outbreak. Saint Thomas Neurosurgical was used as a business conduit designed to enrich Saint Thomas and Howell Allen Clinic while shifting the risk of devastating loss to innocent patients. To the extent that the fiction of a corporate veil exists at all around Saint Thomas Neurosurgical, justice and equity require that said veil be pierced.

DAMAGES

- 277. As a direct and proximate result of the Defendants' wrongful conduct as described above, Carolyn Bland has suffered physical injuries, physical and mental pain and suffering, mental anguish, loss of enjoyment of life and loss of earning capacity.
 - 278. The long term effects of Carolyn Bland's illness are unknown.
- 279. Carolyn Bland remains under the care of physicians. Carolyn and Leon Bland have incurred and continue to incur medical and other expenses.
- 280. As a result of his wife's illness and injuries, Leon Bland has been deprived of and lost the society, services, companionship and consortium of his wife.

PUNITIVE DAMAGES

281. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID AB INITIO

- 282. Plaintiffs seek a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 declaring that the caps on personal injury and punitive damages set forth in Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are an unconstitutional deprivation of the right to trial by jury set forth in Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate and violates the provisions of Article XI, Section 16 of the Constitution of the State of Tennessee which absolutely precludes the Legislature from exercising any legislative power to remove or restrict the right of juries in civil cases to determine damages.
- 283. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages. Tenn. Code Ann. § 29-39-102; and Tenn. Code Ann. § 29-39-104. Under that Act, Plaintiffs' non-economic damages are purportedly capped at \$750,000, and their ability to recover púnitive damages is capped at twice the compensatory damages up to a maximum of \$500,000.
- 284. Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional deprivations of Plaintiffs' constitutionally protected right to trial by jury. Those provisions violate Article I, Section 6 of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate. In addition, the subject statutory caps violate Article I, Section 17 of the Tennessee Constitution which states that all courts shall be open, and every man shall have a remedy for injury done by due course of law and without denial or delay. The subject statutory caps usurp the powers of the Judicial Branch in violation of Article II, Sections 1 & 2 of the Tennessee Constitution. In addition, the subject statutory caps violate Article XI, Section 16 of the Tennessee Constitution which indicates that the rights of

citizens articulated in Tennessee's Bill of Rights "shall never be violated on any pretense whatever... and shall forever remain inviolate."

- 285. Therefore, Carolyn Bland and Leon Bland request a declaration that the statutory caps are unconstitutional, void *ab initio* and of no force and effect.
- 286. Pursuant to Tenn. Code Ann. § 29-14-107, a copy of this Second Amended Complaint is being served on the Attorney General of the State of Tennessee, notifying the State of Tennessee Attorney General that Plaintiffs are challenging the constitutionality of Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104.

PLAINTIFFS' COMPLIANCE WITH TENN. CODE ANN. §§ 29-26-121 AND 29-26-122

- 287. Plaintiffs complied with the notice requirements of Tenn. Code Ann. §§ 29-26-121(a) and provided the required documentation specified in § 29-26-121(a)(2) to appropriate defendants more than 60 days before the filing of the Complaint.
- 288. Plaintiffs have demonstrated their compliance with the provisions of Tenn. Code Ann. §§ 29-26-121(a)(1), 29-26-121(a)(2), 29-26-121(a)(3)(B), 29-26-121(a)(4) and 29-26-121(b) as evidenced by the Affidavit included as Exhibit E, which establishes compliance with Tenn. Code Ann. § 29-26-121 and includes as attachments copies of the Certificates of Mailing from the United States Postal Service stamped with the date of mailing along with copies of the notices sent to the healthcare defendants.
- 289. With regard to Defendant Saint Thomas Neurosurgical, Plaintiffs complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested to Saint Thomas Neurosurgical at both the address for its agent of service of process and the provider's current business address. As set forth in the Affidavit, the

notices were sent to Saint Thomas Neurosurgical on July 26, 2013 by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificates of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.

- 290. With regard to Defendant Howell Allen Clinic, Plaintiffs complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested to Howell Allen Clinic's registered agent. Howell Allen Clinic's current business address is the same as the address of its registered agent. As set forth in the Affidavit, the notice was sent to Howell Allen Clinic on July 26, 2013 by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificate of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.
- 291. With regard to Defendant John Culclasure, M.D., Plaintiffs complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested to John Culclasure, M.D. at the address listed for John Culclasure, M.D. on the Tennessee Department of Health website and John Culclasure, M.D.'s current business addresses. As set forth in the Affidavit, the notice was sent to John Culclasure, M.D. on July 26, 2013 by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificates of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.
- 292. With regard to Defendant Debra Schamberg, R.N., Plaintiffs complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested to Debra Schamberg, R.N. at the address listed for Debra Schamberg, R.N. on the Tennessee Department of Health website and Debra Schamberg, R.N.'s current business addresses. As set forth in the Affidavit, the notice was sent to Debra Schamberg,

R.N. on July 26, 2013 by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificates of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.

- 293. With regard to Defendant Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Plaintiffs complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested, to Saint Thomas West Hospital at both the address for its agent for service of process and the provider's current business address. As set forth in the Affidavit, the notices were sent to Saint Thomas West Hospital on July 26, 2013, by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificates of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.
- 294. With regard to Defendant Saint Thomas Network, Plaintiffs complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested, to Saint Thomas Network at both the address for its agent for service of process and the provider's current business address. As set forth in the Affidavit, the notices were sent to Saint Thomas Network on July 26, 2013, by certified mail, return receipt requested. A copy of the notice and enclosures along with the certificates of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.
- 295. With regard to Defendant Saint Thomas Health, Plaintiffs complied with the requirements of Tenn. Code Ann. § 29-26-121(a) by sending notice of the claim via certified mail, return receipt requested, to Saint Thomas Health's registered agent for service of process. Saint Thomas Health's current business address is the same as the address of its registered agent. As set forth in the Affidavit, the notice was sent to Saint Thomas Health on July 26, 2013, by

certified mail, return receipt requested. A copy of the notice and enclosures along with the certificate of mailing from the United States Postal Service stamped with the date of mailing are attached to the Affidavit.

- 296. The requirements of Tenn. Code Ann. § 29-26-121 have been satisfied.
- 297. Pursuant to Tenn. Code Ann. § 29-26-122(a), a Certificate of Good Faith signed by the undersigned counsel is included as Exhibit F.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Carolyn Bland and Leon Bland request the following relief:

- A. A judgment for compensatory damages in the amount of \$5 Million;
- B. A judgment for punitive damages in an amount to be determined by the trier of fact;
- C. A declaration that the caps found in Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are unconstitutional under Article I, Section 6; Article I, Section 17; Article II, Sections 1 & 2; and/or Article XI, Section 16 of the Constitution of the State of Tennessee and are therefore void ab initio and of no force and effect;
 - D. A jury to determine all disputed factual issues;
 - E. For costs of this cause; and
 - F. For such further relief as the Court may deem just and proper.

Respectfully submitted,

LEADER, BULSO & NOLAN, PLC

William D. Leader, Jr. (B.P.R. No. 09531)
George Nolan (B.P.R. No. 14974)
Paul J. Krog (B.P.R. No. 29263)
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gnolan@leaderbulso.com
pkrog@leaderbulso.com

Attorneys for Plaintiffs Carolyn Bland and Leon Bland

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and a paper copy will be sent by U.S. Mail to those indicated as non-registered participants including

Lela Hollabaugh Attorney for Saint Thomas West Hospital, Saint Thomas Network and Saint Thomas Health Bradley Arant Boult Cummings, LLP 1600 Division Street, Suite 700 Nashville, TN 37203

on this	day of	2013.			
			William D	Leader Ir	 ··· ·

EXHIBIT A

From: Debra Schamberg

Sent: Friday, June 10, 2011 1:34 PM

To: 'John Notarianni'

Subject: RE: NECC Pricing?

Happy Friday John,

If pricing is still \$6.50 for 1ml and \$12 for 2ml for Methylprednisolone 80mg/ml, I am willing to do business with you. Let me know what is needed.

Have a good weekend.

Debra

From: John Notarianni [mailto:jnotarianni@medicalsalesmgmt.com]

Sent: Friday, May 20, 2011 11:57 AM

To: Debra Schamberg
Subject: RE: NECC Pricing?

Debra

How about \$12,00 for the 2 ml of the 80mg/ml methylprednisolone (PF)?

Thank you

John

From: Debra Schamberg [mailto:dschamberg@howeliallen.com]

Sent: Tuesday, May 17, 2011 5:52 PM

To: John Notarianni

Subject: RE: NECC Pricing?

John, if you can get your price under \$6.50 for 1ml vial, then we can talk.

Debra

From: John Notarianni [mailto:jnotarianni@medicalsalesmgmt.com]

Sent: Tuesday, May 17, 2011 10:51 AM

To: Debra Schamberg
Subject: NECC Pricing?

Debra

After our conversations I went back to my manager and he said he really would like to offer you better to earn your business. What price would we need to give you to gain your business on the



Methylprednisolone(PF) 80mg/ml 1ml and 2ml vials. Can you please let me know what price would allow us to work together? Thank you for your patience.

John L. Notarianni Regional Sales Manager Medical Sales Management Representing: NECC Cell Phone: (508)454-0779 Fax: (508) 820-9401

inotarianni@medicalsalesmgmt.com

www.Neccrx.com

NECC - A vital resource for sterile and non-sterile compounding medications.

EXHIBIT B

	Prescription Ord		FA	verly Street, I 800.994.6322 X 888.820.05	, 508.820.	
NAME OF St. Thomas Outpatient is FACILITY: ADDRESS: 1230 Harding Rd S	Neurosurgical Center PHONE NUM	iber: <u>615-</u>	341-3425			
ADDRESS: 1230 Harding Rd S	Suck 901 Nashville, 720 CONTACT N must have Facility name & address to	AME: Debra	Schamberg rescription order - To	P.C).# <u>;50.04</u>	61011
Name of Patient Na	me of medication to be npounded	Strength		Unit size (mL, gm)	# of units	Directions
met	hylprednisolone	80m/m/	pf	1m1	500	`%
me	hylprednisolone Hylprednisolonia	80mg/ml	pf	2m/	200	
		0.				
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Physician's Name/Signature: John	Culclasure, Mo			DEA N	umber: <u> B</u>	10.2226909
Verification: Institutional Agent:	·	CC Use Only	Date:	Ti	me:	

STOPNC_0082

EXHIBIT C



New England Compounding Center, Inc. PO Box 4146

Woburn, MA 01888-4146 Ph. 508-820-0606

Fx. 508-820-1616

Invoice

Date	Invoice #
6/6/2012	217878

Bill To

ST. THOMAS OUTPATIENT NEUROSURGIACL 4230 HARDING ROAD, SUITE 901 NASHVILLE, TN 37205 ATTN: MARLESE ALLEN Ship To

ST. THOMAS OUTPATIENT NEUROSURGIACL 4230 HARDING ROAD, SUITE 901 NASHVILLE, TN 37205 ATTN: DEBRA SCHAMBURG

P.O. Number	Terms	Rep	Ship	Via	F.O.B.		Account#
SC-6-1-12	Net 30	MG-S	6/6/2012	FEDEX			
Quantity	ltem Code		Descriptio	n	Price Eac	h	Amount
500	BETA 6/2 PF METHYL 80/1 PF Shipping Charges	METHYLPRE	SONE repository i DNISOLONE ACI TABLE, 1 ML	nj. (pf) 6mg/ml, 2 ETATE (PF) 80	VOYA-	18.00 6.50 20.00	180.00 3,250.00 20.00
ITHANK YOU FOR	YOUR ORDERIII NVOICE NUMBER (ነለ፤ ኮል ፕለብፎኦነጥ*	***	-	Γotal	•	\$3,4 <i>5</i> 0.00
THEMSE FLACE!	IA A CALCAS TA CAMA DESIGN	ZIA LA LIVIDIAL.			Credits		\$0.00
					3alance Du	е	\$3,450.00



New England Compounding Center, Inc. PO Box 4146

Woburn, MA 01888-4146 Ph. 508-820-0606

Fx. 508-820-1616

Invoice

Date	Invoice #
6/26/2012	220185

Biji To

ST. THOMAS OUTPATIENT NEUROSURGIACL 4230 HARDING ROAD, SUITE 901 NASHVILLE, TN 37205 ATTN: MARLESE ALLEN

Ship To

ST. THOMAS OUTPATIENT NEUROSURGIACL 4230 HARDING ROAD, SUITE 901

NASHVILLE, TN 37205

ATTN: DEBRA SCHAMBURG

P.O. Number	Terms	Rep	Ship	Via	F.O.B.		Account#
SC-6-26-12	Net 30	MG-S	6/26/2012	FEDEX			
Quantity	Item Code		Descriptio	n	Price Ead	eh	Amount
. 1	BETA 6/2 PF METHYL 80/1 PF Shipping Charges	BETAMETHA METHYLPREI MG/ML INJEC	DNISOLONE ACE	nj. (pf) 6mg/ml, 2 m TATE (PF) 80		18.00 6.50 20.00	180.00 3,250.00 20.00
7/3/12 ds iithank you for	YOUR ORDER!!!				otal		
**PLEASE PLACE I	NVOICE NUMBER (N PAYMENT*	**		redits		\$3,450.00
							\$0.00
			•	B	alance Du	le	\$3,450.0



New England Compounding Center, Inc. ing pharmacy solutions PO Box 4146 Woburn, MA 01888-4146 Ph. 508-820-0606

Invoice

Date	Invoice #
7/25/2012	223401

Bill To

ST. THOMAS OUTPATIENT NEUROSURGIACL 4230 HARDING ROAD, SUITE 901

NASHVILLE, TN 37205 ATTN: MARLESE ALLEN Ship To

ST. THOMAS OUTPATIENT NEUROSURGIACL

4230 HARDING ROAD, SUITE 901

NASHVILLE, TN 37205

ATTN: DEBRA SCHAMBURG

P.O. Number	Terms	Rep	Ship	Via	F.O.B.		Account#
SC 7-24-12	Net 30	MG-S	7/25/2012	FEDEX			
Quantity	Item Code		Descriptio	n	. Price Eacl	1	Amount
5.00	BETA 6/2 PF METHYL 80/1 PF Shipping Charges	BETAMETHA METHYLPREI MG/ML INJEC	ONISOLONE ACE	nj. (pf) 6mg/ml, 2 n ETATE (PF) 80		18.00 6.50 20.00	180.00 3,250.00 20.00
THANK YOU FOR				Т	otal		\$3,450.00
TRUBASE PLACET	NVOICE NUMBER (<u></u>	7 · · · · · · · · · · · · · · · · · · ·	С	redits		\$0.00
				В	alance Du		\$3,450.00



New England Compounding Center, Inc. PO Box 4146

Woburn, MA 01888-4146 Ph. 508-820-0606

Invoice

Date	Invoice #
8/13/2012	225489

Bill To

ST. THOMAS OUTPATIENT NEUROSURGICAL 4230 HARDING ROAD, SUITE 901

NASHVILLE, TN 37205 ATTN: MARLESE ALLEN Ship To

ST. THOMAS OUTPATIENT NEUROSURGICAL

4230 HARDING ROAD, SUITE 901

NASHVILLE, TN 37205

ATTN; DEBRA SCHAMBURG

		1				
P.O. Number	Terms	Rep	Ship	Via	F.O.B.	Account#
SC 8-10-12	Net 30	MG-S	8/13/2012	FEDEX		
Quantity	Item Code		Description	n	Price Each	Amount
500.	METHYL 80/1 PF	METHYLPRE MG/ML INJEC	DNISOLONE ACE	ETATE (PF) 80		6.50 3,250.0
1	Shipping Charges	WOMED INSEC	TADLE, I NE		2	0.00 20.0
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HANK YOU FOR	YOUR ORDER!!!		······································			
PLEASE PLACE I	NVOICE NUMBER (ON PAYMENT*	**	10	otal	\$3,270.00
				Cı	redits	\$0.00
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New England Compounding Center, Inc. PO Box 4146 Woburn, MA 01888-4146 Ph. 508-820-0606

Invoice

Date	Invoice #			
8/31/2012	227817			

Bill To

ST. THOMAS OUTPATIENT NEUROSURGICAL 4230 HARDING ROAD, SUITE 901 NASHVILLE, TN 37205

PLEASE PLACE INVOICE NUMBER ON PAYMENT

ATTN: MARLESE ALLEN

Ship To

ST. THOMAS OUTPATIENT NEUROSURGICAL 4230 HARDING ROAD, SUITE 901 NASHVILLE, TN 37205

ATTN: DEBRA SCHAMBURG

P.O. Number	Terms	Rep	Ship	Via	F. O. E	3,	Account#
SC 8-31-12	Net 30	MG-S	8/31/2012	FEDEX			
Quantity	Item Code		Descriptio	n	Pi	rice Each	Amount
500	METHYL 80/1 PF BETA 6/2 PF	MG/ML INJEC	ONISOLONE ACE	······································		6.50	3,250.00
HIGH LANK YOU FOR	VOLD ODDERU			····			
IIITHANK YOU FOR	YOUR ORDER!!!			Т	otal		\$3,430.00

Credits

Balance Due

\$3,430.00

\$0.00

EXHIBIT D

R242 -LIST DAILY CHRT PULL (5) ST THOMAS OP NEUROLOGICAL CENTER LLC CENT # PATIENT NAME PROVIDER ADDRESS TNIT E SAINT THOMAS 65 7.00 L-ESI 1 OF 3 W/JWC ddh B SAINT THOMAS 7.30 3 OF 3 L-EST W/ASA SLD V SATNT THOMAS 7.30 L-ESI 1 OF 3 W/JWC DDH SAINT THOMAS L-ESI 1 OF 3 W/ASA אחמ SAINT THOMAS 8.00 L-EST 1 OF 3 W/ASA DDH SAINT THOMAS 8.00 L-EST 2 OF 3 W/JWC BLD R SAINT THOMAS 3 OF 3 L-ESI W/JWC DDH SAINT THOMAS 8.30 3 OF 3 L-ESI W/ASA SLD E SAINT THOMAS 8.30 L-ESI 2ND INJ W/JWC DDH F SAINT THOMAS 8 -45 L-ESI 2 OF 3 W/JWC DDH 9.00 DIAG LUMB FACET BLK #2 W/J E SAINT THOMAS 66 DDH J SAINT THOMAS 9.00 L-ESI 1 OF 3 W/ASA DDH C SAINT THOMAS 9.30 L-ESI 2 OF 2 W/JWC DDH E SAINT THOMAS 9.30 L-ESI 2 OF 3 W/ASA DDH G SAINT THOMAS 9.45 L-EST 2 OF 3 W/JWC DDH 9.45 3 OF 3 T-ESI W/ASA L SAINT THOMAS SLD 66 10.00 DIAG CERV FACET BLK #1 W/J N SAINT THOMAS DDH K SAINT THOMAS 66 10,00 C-EST 1 OF 3 W/ASA DDH S SAINT THOMAS 66 10.30 3 OF 3 L-ESI W/ASA SLD D SAINT THOMAS 66 10.30 L-ESI 1 OF 3 W/JWC BLD J SAINT THOMAS 66 10.45 L-ESI 2 OF 3 W/JWC DDH 66 10.45 3 OF 3 L-BSI W/ASA N SAINT THOMAS SLD SAINT THOMAS 66 11.00 C-ESI X 1 W/ASA DDH 66 11.30 L-ESI 1 OF 1 REPEAT W/JWC A SAINT THOMAS BLD

66 12.30p L-ESI 2 OF 3 W/ASA

66 12.30p NP/CONSULT-

R SAINT THOMAS

M SAINT THOMAS

MICKEY

SC06912

W/ 4324 NEWBY DR

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BLD

R242 -LIST DAILY CHRT PULL (5) ST THOMAS OF NEUROLOGICAL CENTER LLC		Ļ		
			PA	GE .2
CENT # PATIENT NAME	PROVIDER	LOC TIME REASON	ADDRESS	INIT
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	L SAINT THOMAS	66 1.00p L-ESI 1 OF 3 W/ASA		DDH
CHAPTER TO THE PROPERTY OF	M SAINT THOMAS	66 1.15p L-ESI 2 OF 3 W/JWC		DDH
	SAINT THOMAS	66 1.45p C-ESI 2 OF 3 W/JWC		DDH
	L SAINT THOMAS	66 1.45p 3 OF 3 L-ESI W/ASA		SLD
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	C SAINT THOMAS	66 2.00p L-ESI 1 OF 3 W/ASA		DDH
	J SAINT THOMAS	66 2.30p 3 OF 3 L-ESI W/ASA		SLD
	G SAINT THOMAS	66 2.30p L-ESI REPEAT X 1 W/JWC		HCC
	E SAINT THOMAS	66 2.45p L-ESI 2 OF 2 W/JWC		SLD
	B SAINT THOMAS	66 3.00p L-ESI 1 OF 3 W/ASA		DDH
	C SAINT THOMAS	66 3.30p 3 OF 3 L-ESI W/JWC		DDH
	W SAINT THOMAS	66 3.30p L-ESI 3 OF 3 W/RR		HCC.

EXHIBIT E

AFFIDAVIT OF SANDRA CHADWELL NOURSE

Comes now the affiant, Sandra Chadwell Nourse, who, having first been duly sworn, states that the following statements are true:

- 1. All of the statements contained in this Affidavit are true and correct and made on the basis of my personal knowledge. I am an adult citizen of the State of Tennessee, over the age of 18 years, and am competent to make the statements contained in this Affidavit. I am a legal assistant with Leader, Bulso & Nolan, PLC.
- 2. On July 26, 2013, I mailed by certified mail, return receipt requested a Notice letter and enclosures to Saint Thomas Outpatient Neurosurgical Center, LLC at both the address for the agent for service of process (Gregory B. Lanford, M.D., 2011 Murphy Ave, Ste. 301, Nashville, TN 37203-2023) and the provider's current business address (Floor 9, 4230 Harding Pike, Nashville, TN 37205-2013) and I obtained certificates of mailing from the United States Postal Service stamped with the date of mailing as required by Tennessee Code Annotated § 29-26-121 (a).
- 3. I attach as Exhibit 1 a copy of the Notice letter sent to Saint Thomas Outpatient Neurosurgical Center, LLC along with copies of the enclosures to the letter which include a list of the names and addresses of all healthcare providers who were served Notice pursuant to Tennessee Code Annotated § 29-26-121(a) and a HIPAA compliant medical authorization permitting Saint Thomas Outpatient Neurosurgical Center, LLC to obtain complete medical records from each other provider being sent a notice.

- 4. I attach as Exhibit 2 copies of the Certificates of Mailing from the United States
 Postal Service, stamped with the date of mailing of the Notice and enclosures to Saint Thomas
 Outpatient Neurosurgical Center, LLC.
- 5. On July 26, 2013, I mailed by certified mail, return receipt requested a Notice letter and enclosures to Howell Allen Clinic A Professional Corporation at the address for the agent for service of process (Gregory B. Lanford, M.D., 2011 Murphy Ave., Ste. 301, Nashville, TN 37203-2023) and I obtained a certificate of mailing from the United States Postal Service stamped with the date of mailing as required by Tennessee Code Annotated § 29-26-121 (a).
- 6. I attach as Exhibit 3 a copy of the Notice letter sent to Howell Allen Clinic A Professional Corporation along with copies of the enclosures to the letter which include a list of the names and addresses of all healthcare providers who were served Notice pursuant to Tennessee Code Annotated § 29-26-121(a) and a HIPAA compliant medical authorization permitting Howell Allen Clinic A Professional Corporation to obtain complete medical records from each other provider being sent a notice.
- 7. I attach as Exhibit 4 a copy of the Certificate of Mailing from the United States
 Postal Service, stamped with the date of mailing of the Notice and enclosures to Howell Allen
 Clinic A Professional Corporation.
- 8. On July 26, 2013, I mailed by certified mail, return receipt requested a Notice letter and enclosures to John Weeks Culclasure, M.D. at the address listed for Dr. Culclasure on the Tennessee Department of Health website (Howell Allen Clinic, 2011 Murphy Ave., Suite 301, Nashville, TN 37203) and at the provider's current business address (Saint Thomas Outpatient Neurosurgical Center, 4230 Harding Pike, Suite 901, Nashville, TN 37205) and I

obtained certificates of mailing from the United States Postal Service stamped with the date of mailing as required by Tennessee Code Annotated § 29-26-121 (a).

- 9. I attach as Exhibit 5 a copy of the Notice letter sent to John Weeks Culclasure, M.D. along with copies of the enclosures to the letter which include a list of the names and addresses of all healthcare providers who were served Notice pursuant to Tennessee Code Annotated § 29-26-121(a) and a HIPAA compliant medical authorization permitting John Weeks Culclasure, M.D. to obtain complete medical records from each other provider being sent a notice.
- 10. I attach as Exhibit 6 copies of the Certificates of Mailing from the United States Postal Service, stamped with the date of mailing of the Notice and enclosures to John Weeks Culclasure, M.D.
- 11. On July 26, 2013, I mailed by certified mail, return receipt requested a Notice letter and enclosures to Debra V. Schamberg, R.N. at the address listed for Ms. Schamberg on the Tennessee Department of Health website (Nashville, TN 37217) and at the provider's current business addresses (Howell Allen Clinic, 2011 Murphy Ave., Suite 301, Nashville, TN 37203 and Saint Thomas Outpatient Neurosurgical Center, 4230 Harding Pike, Suite 901, Nashville, TN 37205) and I obtained certificates of mailing from the United States Postal Service stamped with the date of mailing as required by Tennessee Code Annotated § 29-26-121 (a).
- 12. I attach as Exhibit 7 a copy of the Notice letter sent to Debra V. Schamberg, R.N. along with copies of the enclosures to the letter which include a list of the names and addresses of all healthcare providers who were served Notice pursuant to Tennessee Code Annotated

- § 29-26-121(a) and a HIPAA compliant medical authorization permitting Debra V. Schamberg, R.N. to obtain complete medical records from each other provider being sent a notice.
- 13. I attach as Exhibit 8 copies of the Certificates of Mailing from the United States Postal Service, stamped with the date of mailing of the Notice and enclosures to Debra V. Schamberg, R.N.
- 14. On July 26, 2013, I mailed by certified mail, return receipt requested a Notice letter and enclosures to Saint Thomas West Hospital at both the address for the agent for service of process (E. Berry Holt III, Ste 800, 102 Woodmont Blvd., Nashville, TN 37205-2221) and the provider's current business address (4220 Harding Pike, Nashville, TN 37205-2005) and I obtained certificates of mailing from the United States Postal Service stamped with the date of mailing as required by Tennessee Code Annotated § 29-26-121 (a).
- 15. I attach as Exhibit 9 a copy of the Notice letter sent to Saint Thomas West Hospital along with copies of the enclosures to the letter which include a list of the names and addresses of all healthcare providers who were served Notice pursuant to Tennessee Code Annotated § 29-26-121(a) and a HIPAA compliant medical authorization permitting Saint Thomas West Hospital to obtain complete medical records from each other provider being sent a notice.
- 16. I attach as Exhibit 10 copies of the Certificates of Mailing from the United States Postal Service, stamped with the date of mailing of the Notice and enclosures to Saint Thomas West Hospital.
- 17. On July 26, 2013, I mailed by certified mail, return receipt requested a Notice letter and enclosures to Saint Thomas Network at both the address for the agent for service of

process (E. Berry Holt III, Ste 800, 102 Woodmont Blvd., Nashville, TN 37205-2221) and the provider's current business address (4220 Harding Pike, Nashville, TN 37205-2005) and I obtained certificates of mailing from the United States Postal Service stamped with the date of mailing as required by Tennessee Code Annotated § 29-26-121 (a).

- 18. I attach as Exhibit 11 a copy of the Notice letter sent to Saint Thomas Network along with copies of the enclosures to the letter which include a list of the names and addresses of all healthcare providers who were served Notice pursuant to Tennessee Code Annotated § 29-26-121(a) and a HIPAA compliant medical authorization permitting Saint Thomas Network to obtain complete medical records from each other provider being sent a notice.
- 19. I attach as Exhibit 12 copies of the Certificates of Mailing from the United States

 Postal Service, stamped with the date of mailing of the Notice and enclosures to Saint Thomas

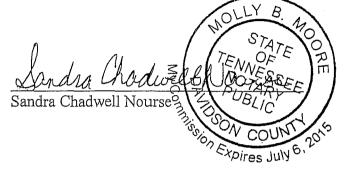
 Network.
- 20. On July 26, 2013, I mailed by certified mail, return receipt requested a Notice letter and enclosures to Saint Thomas Health at the address for the agent for service of process (E. Berry Holt III, Ste 800, 102 Woodmont Blvd., Nashville, TN 37205-2221) and I obtained a certificate of mailing from the United States Postal Service stamped with the date of mailing as required by Tennessee Code Annotated § 29-26-121 (a).
- 21. I attach as Exhibit 13 a copy of the Notice letter sent to Saint Thomas Health along with copies of the enclosures to the letter which include a list of the names and addresses of all healthcare providers who were served Notice pursuant to Tennessee Code Annotated § 29-26-121(a) and a HIPAA compliant medical authorization permitting Saint Thomas Health to obtain complete medical records from each other provider being sent a notice.

22. I attach as Exhibit 14 a copy of the Certificate of Mailing from the United States

Postal Service, stamped with the date of mailing of the Notice and enclosures to Saint Thomas

Health.

FURTHER AFFIANT SAITH NOT.



STATE OF TENNESSEE

COUNTY OF DAVIDSON

Sworn to and subscribed before me this 18th day of September, 2013.

Notary Public

My Commission Expires: July 6, 2015

Leader, Bulso & Nolan, PLC

Attorneys at Law

WILLIAM D. LEADER, JR. Direct Dial: 615-780-4111 Direct Fax: 615-780-4121 bleader@leaderbulso.com

REDACTED

July 26, 2013

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Saint Thomas Outpatient Neurosurgical Center, LLC Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave, Ste 301 Nashville, TN 37203-2023

Saint Thomas Outpatient Neurosurgical Center, LLC Floor 9
4230 Harding Pike
Nashville, TN 37205-2013

Re: Caroly

Carolyn E. Bland

Notice of health care liability claim required by

Tennessee Code Annotated § 29-26-121

To Saint Thomas Outpatient Neurosurgical Center, LLC:

We are the attorneys representing Carolyn E. Bland and Leon Bland.

Through their attorneys, Carolyn E. Bland and Leon Bland are asserting potential claims for health care liability against Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic A Professional Corporation, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, John Weeks Culclasure, M.D., Debra V. Schamberg, R.N. and Patricia G. Beckham, including their agents, employees, physicians, nurses and pharmacists.

This potential claim arises out of care, medicines and services provided by employees and/or agents of Saint Thomas Outpatient Neurosurgical Center, LLC to Carolyn E. Bland from August 2012 through October 2012.

The full name and date of birth of the patient whose treatment is at issue:

Carolyn Elaine Ford Bland Date of Birth: 1946

{00062532.DOCX / ver: }

Case 1:13-md-02419-RWZ Document 468-1 Filed 10/02/13 Page 81 of 137

Saint Thomas Outpatient Neurosurgical Center, LLC July 26, 2013 Page 2

The names and address of the claimants authorizing this notice:

Carolyn E. Bland and Roy Leon Bland, husband of Carolyn E. Bland 1160 Old Canton Pike Cadiz, Kentucky 42211

The name and address of the attorney sending this notice:

William D. Leader, Jr. Leader, Bulso & Nolan, PLC 414 Union Street, Suite 1740 Nashville, Tennessee 37219

Attached hereto is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D).

Pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(E), I also enclose a HIPAA compliant medical authorization permitting you to obtain complete medical records on Carolyn E. Bland from each other provider being sent a notice. If any of those providers does not accept this authorization for any reason, please contact us and we will arrange to execute an authorization acceptable to them that will permit you to obtain complete medical records on Carolyn E. Bland.

Neither this notice nor the medical authorization waives the common law physician patient privilege concerning the care and treatment of Carolyn E. Bland by any doctor who provided medical services for Carolyn E. Bland. We expect that you will not communicate with any person other than your attorney about any doctor's care and treatment of Carolyn E. Bland.

We believe this letter complies with the letter and spirit of Tennessee Code Annotated § 29-26-121. If you believe it is deficient in any way, please let us know and any defect will be promptly cured. If we do not hear from you we will assume that you agree the letter complies with the law.

Very truly yours,

William D. Leader, Jr.

WDL/ Enclosures List of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D)

Re: Carolyn E. Bland and Leon Bland, husband of Carolyn E. Bland

Below is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D) of a potential claim for health care liability:

Saint Thomas Outpatient Neurosurgical Center, LLC Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave, Ste 301 Nashville, TN 37203-2023

Saint Thomas Outpatient Neurosurgical Center, LLC Floor 9
4230 Harding Pike
Nashville, TN 37205-2013

Howell Allen Clinic A Professional Corporation Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave., Ste 301 Nashville, TN 37203-2023

Saint Thomas West Hospital
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas West Hospital 4220 Harding Pike Nashville, TN 37205-2005

Saint Thomas Network
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas Network 4220 Harding Pike Nashville, TN 37205-2005 Saint Thomas Health
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

John Weeks Culclasure, M.D. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

John Weeks Culclasure, M.D. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Debra V. Schamberg, R.N. Nashville, TN 37217

Debra V. Schamberg, R.N. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

Debra V. Schamberg, R.N. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Patricia G. Beckham Baptist Women's Pavillion 2011 Murphy Ave. Nashville, TN 37203

Patricia G. Beckham The Hospital for Spinal Surgery 2011 Murphy Ave., Suite 400 Nashville, TN 37203

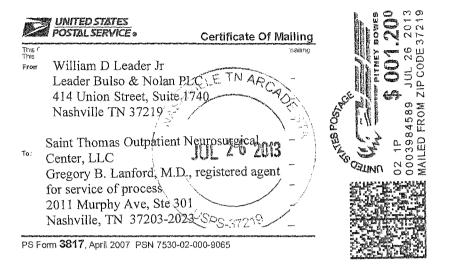
LIMITED AUTHORIZATION TO DISCLOSE MEDICAL INFORMATION OR RECORDS

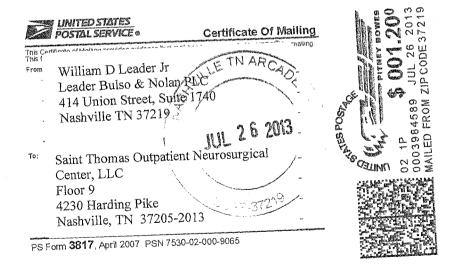


By signing below, I hereby request and authorize the Health Care Provider identified below to disclose certain information (the "Information") as provided in this Authorization. Information To Be Used Or Disclosed Patient Identifier: DOB: 1946 Patient Name: Carolyn E. Bland Description of Information: Any and all medical information and records, or true and correct copies thereof, in your possession, custody or control, including, but not limited to, medical histories, records, reports, summaries, diagnosis. prognoses, records of treatment and medication ordered and/or given, entries, letters or correspondence to other physicians, electrocardiograms, x-ray films and reports, ultrasounds, diagnostic imaging studies, laboratory data and records, pathological reports, slides and specimens, prescription records, insurance records, bills or statements of account, incident reports, birth certificates, death certificates and all other written or graphic data prepared, kept, made or maintained in your possession, custody or control and summaries of injuries, treatment and prognosis, if requested. that pertain to the Patient. THIS AUTHORIZATION DOES NOT AUTHORIZE VERBAL COMMUNICATIONS WITH THE REFERENCED INDIVIDUAL OR ORGANIZATION. Persons Or Organizations Authorized To Disclose The Information Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic A Professional Health Care Provider. Corporation: Saint Thomas West Hospital; John Weeks Culclasure, M.D.; Debra V. Schamberg, R.N.; Saint Thomas Network: Saint Thomas Health: Patricia G. Beckham I authorize the Health Care Provider(s) and its employees and agents to disclose the Information as provided in this Authorization. A photostatic copy of this Authorization is to be considered as effective as the original. I understand that I am not required to sign this Authorization. The Health Care Provider will not condition treatment, payment, enrollment or eligibility for benefits on whether I sign this Authorization. Persons or Organizations Authorized to Receive the Information Saint Thomas Outpatient Neurosurgical Center, LLC or any representative, attorney or investigator from said organization, c/o Gregory B. Lanford, M.D., 2011 Murphy Ave, Ste 301, Nashville, TN 37203-2023 or Floor 9, 4230 Harding Pike, Nashville, TN 37205-2013. Purpose of the Requested Use or Disclosure At the regulat of the individual Expiration and Revocation of This Authorization Expiration Date or Event: 7-25-14 I understand that I may revoke this Authorization at any time prior to the expiration date or event, but that my revocation will not have any affect on actions taken by the Health Care Provider, its employees or agents before they received my revocation. Should I desire to revoke this Authorization, I must send written notice to the Health Care Provider at the following address: I understand that I may see and copy the Information if I ask for it. I understand that any Information released may be subject to re-disclosure, by the recipient and may no longer be protected by federal or state privacy law or regulations. Signature (Authorized Representative) Date Signature (Patient)

Relationship to Patient

Signature (Witness)





Leader, Bulso & Nolan, PLC

Attorneys at Law

WILLIAM D. LEADER, JR. Direct Dial: 615-780-4111 Direct Fax: 615-780-4121 bleader@leaderbulso.com

July 26, 2013



CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Howell Allen Clinic A Professional Corporation Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave., Ste 301 Nashville, TN 37203-2023

Re:

Carolyn E. Bland

Notice of health care liability claim required by

Tennessee Code Annotated § 29-26-121

To Howell Allen Clinic A Professional Corporation:

We are the attorneys representing Carolyn E. Bland and Leon Bland.

Through their attorneys, Carolyn E. Bland and Leon Bland are asserting potential claims for health care liability against Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic A Professional Corporation, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, John Weeks Culclasure, M.D., Debra V. Schamberg, R.N. and Patricia G. Beckham, including their agents, employees, physicians, nurses and pharmacists.

This potential claim arises out of care, medicines and services provided by employees and/or agents of Howell Allen Clinic A Professional Corporation to Carolyn E. Bland from August 2012 through October 2012.

The full name and date of birth of the patient whose treatment is at issue:

Carolyn Elaine Ford Bland
Date of Birth: 1946

The names and address of the claimants authorizing this notice:

Carolyn E. Bland and Roy Leon Bland, husband of Carolyn E. Bland 1160 Old Canton Pike Cadiz, Kentucky 42211

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Howell Allen Clinic A Professional Corporation July 26, 2013 Page 2

The name and address of the attorney sending this notice:

William D. Leader, Jr. Leader, Bulso & Nolan, PLC 414 Union Street, Suite 1740 Nashville, Tennessee 37219

Attached hereto is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D).

Pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(E), I also enclose a HIPAA compliant medical authorization permitting you to obtain complete medical records on Carolyn E. Bland from each other provider being sent a notice. If any of those providers does not accept this authorization for any reason, please contact us and we will arrange to execute an authorization acceptable to them that will permit you to obtain complete medical records on Carolyn E. Bland.

Neither this notice nor the medical authorization waives the common law physician patient privilege concerning the care and treatment of Carolyn E. Bland by any doctor who provided medical services for Carolyn E. Bland. We expect that you will not communicate with any person other than your attorney about any doctor's care and treatment of Carolyn E. Bland.

We believe this letter complies with the letter and spirit of Tennessee Code Annotated § 29-26-121. If you believe it is deficient in any way, please let us know and any defect will be promptly cured. If we do not hear from you we will assume that you agree the letter complies with the law.

Very truly yours,

William D. Leader, Jr.

WDL/ Enclosures List of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D)

Re: Carolyn E. Bland and Leon Bland, husband of Carolyn E. Bland

Below is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D) of a potential claim for health care liability:

Saint Thomas Outpatient Neurosurgical Center, LLC Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave, Ste 301 Nashville, TN 37203-2023

Saint Thomas Outpatient Neurosurgical Center, LLC Floor 9 4230 Harding Pike Nashville, TN 37205-2013

Howell Allen Clinic A Professional Corporation Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave., Ste 301 Nashville, TN 37203-2023

Saint Thomas West Hospital
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas West Hospital 4220 Harding Pike Nashville, TN 37205-2005

Saint Thomas Network
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas Network 4220 Harding Pike Nashville, TN 37205-2005 Saint Thomas Health
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

John Weeks Culclasure, M.D. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

John Weeks Culclasure, M.D. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Debra V. Schamberg, R.N. Nashville, TN 37217

Debra V. Schamberg, R.N. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

Debra V. Schamberg, R.N. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Patricia G. Beckham Baptist Women's Pavillion 2011 Murphy Ave. Nashville, TN 37203

Patricia G. Beckham The Hospital for Spinal Surgery 2011 Murphy Ave., Suite 400 Nashville, TN 37203

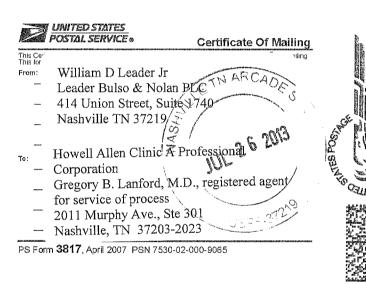
LIMITED AUTHORIZATION TO DISCLOSE MEDICAL INFORMATION OR RECORDS



By signing below, I hereby request and authorize the Health Care Provider identified below to disclose certain information (the "Information") as provided in this Authorization. Information To Be Used Or Disclosed Patient Name: Carolyn E. Bland Patient Identifier: DOB: 1946 Description of Information: Any and all medical information and records, or true and correct copies thereof, in your possession, custody or control, including, but not limited to, medical histories, records, reports, summaries, diagnosis. prognoses, records of treatment and medication ordered and/or given, entries, letters or correspondence to other physicians, electrocardiograms, x-ray films and reports, ultrasounds, diagnostic imaging studies, laboratory data and records, pathological reports, slides and specimens, prescription records, insurance records, bills or statements of account, incident reports, birth certificates, death certificates and all other written or graphic data prepared, kept, made or maintained in your possession, custody or control and summaries of injuries, treatment and prognosis, if requested, that pertain to the Patient. THIS AUTHORIZATION DOES NOT AUTHORIZE VERBAL COMMUNICATIONS WITH THE REFERENCED INDIVIDUAL OR ORGANIZATION. Persons Or Organizations Authorized To Disclose The Information Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic A Professional Health Care Provider. Corporation; Saint Thomas West Hospital; John Weeks Culclasure, M.D.; Debra V. Schamberg, R.N.; Saint Thomas Network; Saint Thomas Health; Patricia G. Beckham I authorize the Health Care Provider(s) and its employees and agents to disclose the Information as provided in this Authorization. A photostatic copy of this Authorization is to be considered as effective as the original. I understand that I am not required to sign this Authorization. The Health Care Provider will not condition treatment, payment, enrollment or eligibility for benefits on whether I sign this Authorization. Persons or Organizations Authorized to Receive the Information Howell Allen Clinic A Professional Corporation or any representative, attorney or investigator from said organization, c/o Gregory B. Lanford, M.D., 2011 Murphy Ave, Ste 301, Nashville, TN 37203-2023. Purpose of the Requested Use or Disclosure At the request of the individual Expiration and Revocation of This Authorization Expiration Date or Event: __ 7-25-14 I understand that I may revoke this Authorization at any time prior to the expiration date or event, but that my revocation will not have any affect on actions taken by the Health Care Provider, its employees or agents before they received my revocation. Should I desire to revoke this Authorization, I must send written notice to the Health Care Provider at the following address: I understand that I may see and copy the Information if I ask for it. I understand that any Information released may be subject to re-disclosure by the recipient and may no longer be protected by federal or state privacy law or regulations. Signature (Authorized Representative) Date Signature (Patient)

Relationship to Patient

Signature (Witness)



Leader, Bulso & Nolan, PLC

Attorneys at Law

WILLIAM D. LEADER, JR. Direct Dial: 615-780-4111 Direct Fax: 615-780-4121 bleader@leaderbulso.com

July 26, 2013



CERTIFIED MAIL, RETURN RECEIPT REQUESTED

John Weeks Culclasure, M.D. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

John Weeks Culclasure, M.D. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Re:

Carolyn E. Bland

Notice of health care liability claim required by

Tennessee Code Annotated § 29-26-121

Dear Dr. Culclasure:

We are the attorneys representing Carolyn E. Bland and Leon Bland.

Through their attorneys, Carolyn E. Bland and Leon Bland are asserting potential claims for health care liability against Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic A Professional Corporation, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, John Weeks Culclasure, M.D., Debra V. Schamberg, R.N. and Patricia G. Beckham, including their agents, employees, physicians, nurses and pharmacists.

This potential claim arises out of care, medicines and services provided by you, your employees and/or agents to Carolyn E. Bland from August 2012 through October 2012.

The full name and date of birth of the patient whose treatment is at issue:

Carolyn Elaine Ford Bland
Date of Birth: 946

{00062535.DOCX / ver: }

Case 1:13-md-02419-RWZ Document 468-1 Filed 10/02/13 Page 97 of 137

John Weeks Culclasure, M.D. July 26, 2013 Page 2

The names and address of the claimants authorizing this notice:

Carolyn E. Bland and Roy Leon Bland, husband of Carolyn E. Bland 1160 Old Canton Pike
Cadiz, Kentucky 42211

The name and address of the attorney sending this notice:

William D. Leader, Jr. Leader, Bulso & Nolan, PLC 414 Union Street, Suite 1740 Nashville, Tennessee 37219

Attached hereto is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D).

Pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(E), I also enclose a HIPAA compliant medical authorization permitting you to obtain complete medical records on Carolyn E. Bland from each other provider being sent a notice. If any of those providers does not accept this authorization for any reason, please contact us and we will arrange to execute an authorization acceptable to them that will permit you to obtain complete medical records on Carolyn E. Bland.

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We believe this letter complies with the letter and spirit of Tennessee Code Annotated § 29-26-121. If you believe it is deficient in any way, please let us know and any defect will be promptly cured. If we do not hear from you we will assume that you agree the letter complies with the law.

Very truly yours,

Bilteadn

William D. Leader, Jr.

WDL/ Enclosures List of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D)

Re: Carolyn E. Bland and Leon Bland, husband of Carolyn E. Bland

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Saint Thomas Outpatient Neurosurgical Center, LLC Floor 9
4230 Harding Pike
Nashville, TN 37205-2013

Howell Allen Clinic A Professional Corporation Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave., Ste 301 Nashville, TN 37203-2023

Saint Thomas West Hospital E. Berry Holt III, registered agent for service of process Ste 800 102 Woodmont Blvd. Nashville, TN 37205-2221

Saint Thomas West Hospital 4220 Harding Pike Nashville, TN 37205-2005

Saint Thomas Network
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Debra V. Schamberg, R.N. Nashville, TN 37217

Debra V. Schamberg, R.N. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

Debra V. Schamberg, R.N. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Patricia G. Beckham Baptist Women's Pavillion 2011 Murphy Ave. Nashville, TN 37203

Patricia G. Beckham The Hospital for Spinal Surgery 2011 Murphy Ave., Suite 400 Nashville, TN 37203

LIMITED AUTHORIZATION TO DISCLOSE MEDICAL INFORMATION OR RECORDS

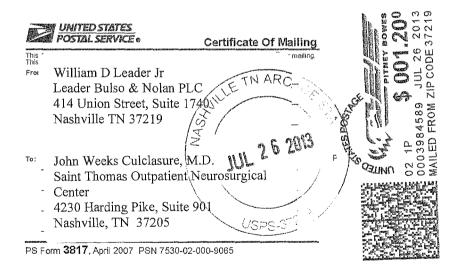


By signing below, I hereby request and authorize the Health Care Provider identified below to disclose certain information (the "Information") as provided in this Authorization. Information To Be Used Or Disclosed Patient Name: Carolyn E. Bland Patient Identifier: DOB: 1946 Description of Information: Any and all medical information and records, or true and correct copies thereof, in your possession, custody or control, including, but not limited to, medical histories, records, reports, summaries, diagnosis. prognoses, records of treatment and medication ordered and/or given, entries, letters or correspondence to other physicians, electrocardiograms, x-ray films and reports, ultrasounds, diagnostic imaging studies, laboratory data and records, pathological reports, slides and specimens, prescription records, insurance records, bills or statements of account, incident reports, birth certificates, death certificates and all other written or graphic data prepared, kept, made or maintained in your possession, custody or control and summaries of injuries, treatment and prognosis, if requested. that pertain to the Patient. THIS AUTHORIZATION DOES NOT AUTHORIZE VERBAL COMMUNICATIONS WITH THE REFERENCED INDIVIDUAL OR ORGANIZATION. Persons Or Organizations Authorized To Disclose The Information Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic A Professional Health Care Provider. Corporation; Saint Thomas West Hospital; John Weeks Culclasure, M.D.; Debra V. Schamberg, R.N.; Saint Thomas Network: Saint Thomas Health: Patricia G. Beckham I authorize the Health Care Provider(s) and its employees and agents to disclose the Information as provided in this Authorization. A photostatic copy of this Authorization is to be considered as effective as the original. I understand that I am not required to sign this Authorization. The Health Care Provider will not condition treatment, payment, enrollment or eligibility for benefits on whether I sign this Authorization. Persons or Organizations Authorized to Receive the Information John Weeks Culclasure, M.D. or his representative, attorney or investigator, Howell Allen Clinic, 2011 Murphy Ave. Suite 301, Nashville, TN 37203 or 4230 Harding Pike, Suite 901, Nashville, TN 37205. Purpose of the Requested Use or Disclosure the regions of the individual Expiration and Revocation of This Authorization Expiration Date or Event: 7-25-14 I understand that I may revoke this Authorization at any time prior to the expiration date or event, but that my revocation will not have any affect on actions taken by the Health Care Provider, its employees or agents before they received my revocation. Should I desire to revoke this Authorization, I must send written notice to the Health Care Provider at the following address: I understand that I may see and copy the Information if I ask for it. I understand that any Information released may be subject to re-disclosure by the recipient and may no longer be protected by federal or state privacy law or regulations. Signature (Authorized Representative) Date Signature (Patient)

Relationship to Patient .

Signature (Witness)





Leader, Bulso & Nolan, PLC

Attorneys at Law

WILLIAM D. LEADER, JR. Direct Dial: 615-780-4111 Direct Fax: 615-780-4121 bleader@leaderbulso.com

REDACTED

July 26, 2013

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Debra V. Schamberg, R.N. Nashville, TN 37217

Debra V. Schamberg, R.N. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

Debra V. Schamberg, R.N. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

> Carolyn E. Bland Re:

> > Notice of health care liability claim required by

Tennessee Code Annotated § 29-26-121

Dear Ms. Schamberg:

We are the attorneys representing Carolyn E. Bland and Leon Bland.

Through their attorneys, Carolyn E. Bland and Leon Bland are asserting potential claims for health care liability against Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic A Professional Corporation, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, John Weeks Culclasure, M.D., Debra V. Schamberg, R.N. and Patricia G. Beckham, including their agents, employees, physicians, nurses and pharmacists.

This potential claim arises out of care, medicines and services provided by you, your employees and/or agents to Carolyn E. Bland from August 2012 through October 2012.

The full name and date of birth of the patient whose treatment is at issue:

Carolyn Elaine Ford Bland Date of Birth: 1946

{00062537.DOCX / yer: }

Debra V. Schamberg, R.N. July 26, 2013 Page 2

The names and address of the claimants authorizing this notice:

Carolyn E. Bland and Roy Leon Bland, husband of Carolyn E. Bland 1160 Old Canton Pike Cadiz, Kentucky 42211

The name and address of the attorney sending this notice:

William D. Leader, Jr. Leader, Bulso & Nolan, PLC 414 Union Street, Suite 1740 Nashville, Tennessee 37219

Attached hereto is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D).

Pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(E), I also enclose a HIPAA compliant medical authorization permitting you to obtain complete medical records on Carolyn E. Bland from each other provider being sent a notice. If any of those providers does not accept this authorization for any reason, please contact us and we will arrange to execute an authorization acceptable to them that will permit you to obtain complete medical records on Carolyn E. Bland.

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We believe this letter complies with the letter and spirit of Tennessee Code Annotated § 29-26-121. If you believe it is deficient in any way, please let us know and any defect will be promptly cured. If we do not hear from you we will assume that you agree the letter complies with the law.

Very truly yours,

William D. Leader, Jr.

WDL/ Enclosures List of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D)

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Saint Thomas West Hospital
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas West Hospital 4220 Harding Pike Nashville, TN 37205-2005

Saint Thomas Network
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Saint Thomas Network 4220 Harding Pike Nashville, TN 37205-2005 Saint Thomas Health
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John Weeks Culclasure, M.D. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

John Weeks Culclasure, M.D. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Debra V. Schamberg, R.N. Nashville, TN 37217

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Debra V. Schamberg, R.N. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

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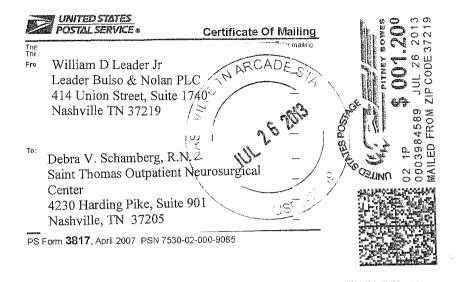
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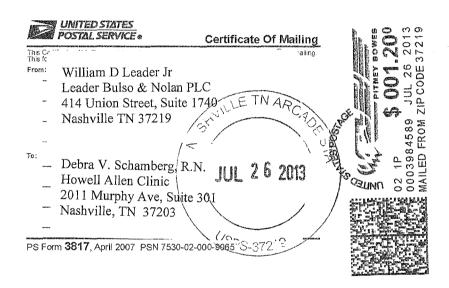


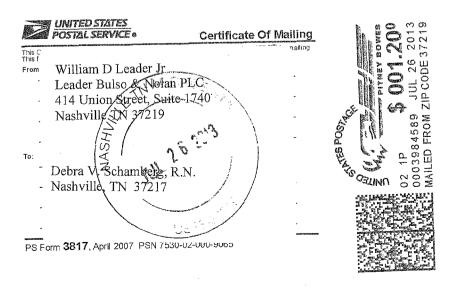
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Relationship to Patient

Signature (Witness)







Leader, Bulso & Nolan, PLC

Attorneys at Law

WILLIAM D. LEADER, JR. Direct Dial: 615-780-4111 Direct Fax: 615-780-4121 bleader@leaderbulso.com

REDACTED

July 26, 2013

CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Saint Thomas West Hospital

E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas West Hospital 4220 Harding Pike Nashville, TN 37205-2005

Re:

Carolyn E. Bland

Notice of health care liability claim required by

Tennessee Code Annotated § 29-26-121

To Saint Thomas West Hospital:

We are the attorneys representing Carolyn E. Bland and Leon Bland.

Through their attorneys, Carolyn E. Bland and Leon Bland are asserting potential claims for health care liability against Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic A Professional Corporation, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, John Weeks Culclasure, M.D., Debra V. Schamberg, R.N. and Patricia G. Beckham, including their agents, employees, physicians, nurses and pharmacists.

This potential claim arises out of care, medicines and services provided by employees and/or agents of Saint Thomas West Hospital formerly known as St. Thomas Hospital to Carolyn E. Bland from August 2012 through October 2012.

The full name and date of birth of the patient whose treatment is at issue:

Carolyn Elaine Ford Bland Date of Birth: 1946

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414 Union Street, Suite 1740, Nashville, Tennessee 37219-1734

Tel: 615.780.4100

www.leaderbulso.com

Case 1:13-md-02419-RWZ Document 468-1 Filed 10/02/13 Page 113 of 137

Saint Thomas West Hospital July 26, 2013 Page 2

The names and address of the claimants authorizing this notice:

Carolyn E. Bland and Roy Leon Bland, husband of Carolyn E. Bland 1160 Old Canton Pike Cadiz, Kentucky 42211

The name and address of the attorney sending this notice:

William D. Leader, Jr. Leader, Bulso & Nolan, PLC 414 Union Street, Suite 1740 Nashville, Tennessee 37219

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LIMITED AUTHORIZATION TO DISCLOSE MEDICAL INFORMATION OR RECORDS

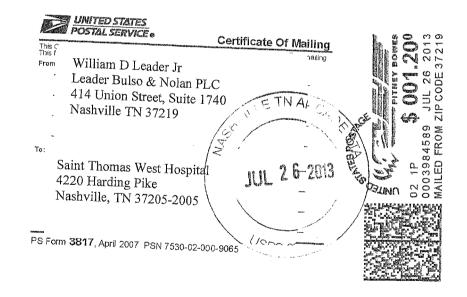


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Relationship to Patient

Signature (Witness)





Leader, Bulso & Nolan, PLC

Attorneys at Law

WILLIAM D. LEADER, JR. Direct Dial: 615-780-4111 Direct Fax: 615-780-4121 bleader@leaderbulso.com

July 26, 2013



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E. Berry Holt III, registered agent for service of process
Ste 800
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Nashville, TN 37205-2221

Saint Thomas Network 4220 Harding Pike Nashville, TN 37205-2005

Re:

Carolyn E. Bland

Notice of health care liability claim required by

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The full name and date of birth of the patient whose treatment is at issue:

Carolyn Elaine Ford Bland
Date of Birth: 1946

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Saint Thomas Network July 26, 2013 Page 2

The names and address of the claimants authorizing this notice:

Carolyn E. Bland and Roy Leon Bland, husband of Carolyn E. Bland 1160 Old Canton Pike Cadiz, Kentucky 42211

The name and address of the attorney sending this notice:

William D. Leader, Jr. Leader, Bulso & Nolan, PLC 414 Union Street, Suite 1740 Nashville, Tennessee 37219

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Very truly yours,

William D. Leader, Jr.

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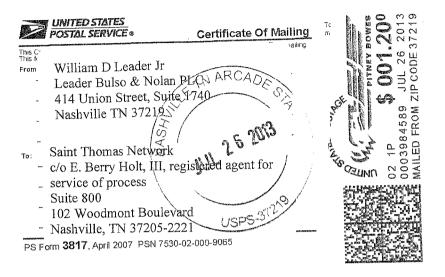
LIMITED AUTHORIZATION TO DISCLOSE MEDICAL INFORMATION OR RECORDS

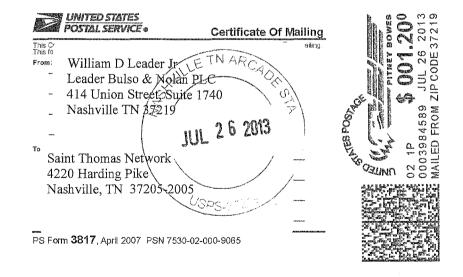


By signing below, I hereby request and authorize the Health Care Provider identified below to disclose certain information (the "Information") as provided in this Authorization. Information To Be Used Or Disclosed Patient Name: Carolyn E. Bland Patient Identifier: DOB: 1946 Description of Information: Any and all medical information and records, or true and correct copies thereof, in your possession, custody or control, including, but not limited to, medical histories, records, reports, summaries, diagnosis, prognoses, records of treatment and medication ordered and/or given, entries, letters or correspondence to other physicians, electrocardiograms, x-ray films and reports, ultrasounds, diagnostic imaging studies, laboratory data and records, pathological reports, slides and specimens, prescription records, insurance records, bills or statements of account, incident reports, birth certificates, death certificates and all other written or graphic data prepared, kept, made or maintained in your possession, custody or control and summaries of injuries, treatment and prognosis, if requested. that pertain to the Patient. THIS AUTHORIZATION DOES NOT AUTHORIZE VERBAL COMMUNICATIONS WITH THE REFERENCED INDIVIDUAL OR ORGANIZATION. Persons Or Organizations Authorized To Disclose The Information Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic A Professional Health Care Provider. Corporation; Saint Thomas West Hospital; John Weeks Culclasure, M.D.; Debra V. Schamberg, R.N.: Saint Thomas Network: Saint Thomas Health; Patricia G. Beckham I authorize the Health Care Provider(s) and its employees and agents to disclose the Information as provided in this Authorization. A photostatic copy of this Authorization is to be considered as effective as the original. I understand that I am not required to sign this Authorization. The Health Care Provider will not condition treatment, payment, enrollment or eligibility for benefits on whether I sign this Authorization. Persons or Organizations Authorized to Receive the Information Saint Thomas Network or any representative, attorney or investigator from said organization, c/o E. Berry Holt III. Ste 800, 102 Woodmont Blvd., Nashville, TN 37205-2221 or 4220 Harding Pike, Nashville, TN 37205-2005. Purpose of the Requested Use or Disclosure At the reguest of the individual Expiration and Revocation of This Authorization Expiration Date or Event: _]-25-14 I understand that I may revoke this Authorization at any time prior to the expiration date or event, but that my revocation will not have any affect on actions taken by the Health Care Provider, its employees or agents before they received my revocation. Should I desire to revoke this Authorization, I must send written notice to the Health Care Provider at the following address: I understand that I may see and copy the Information if I ask for it. I understand that any Information released may be subject to re-disclosure by the recipient and may no longer be protected by federal or state privacy law or regulations. Signature (Authorized Representative) Date Signature (Patient)

Relationship to Patient

Signature (Witness)





Leader, Bulso & Nolan, PLC

Attorneys at Law

WILLIAM D. LEADER, JR. Direct Dial: 615-780-4111 Direct Fax: 615-780-4121 bleader@leaderbulso.com

July 26, 2013



CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Saint Thomas Health
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Re:

Carolyn E. Bland

Notice of health care liability claim required by

Tennessee Code Annotated § 29-26-121

To Saint Thomas Health:

We are the attorneys representing Carolyn E. Bland and Leon Bland.

Through their attorneys, Carolyn E. Bland and Leon Bland are asserting potential claims for health care liability against Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic A Professional Corporation, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, John Weeks Culclasure, M.D., Debra V. Schamberg, R.N. and Patricia G. Beckham, including their agents, employees, physicians, nurses and pharmacists.

This potential claim arises out of care, medicines and services provided by employees and/or agents of Saint Thomas Health to Carolyn E. Bland from August 2012 through October 2012.

The full name and date of birth of the patient whose treatment is at issue:

Carolyn Elaine Ford Bland
Date of Birth: 1946

{00062541.DOCX / ver: }

Saint Thomas Health July 26, 2013 Page 2

The names and address of the claimants authorizing this notice:

Carolyn E. Bland and Roy Leon Bland, husband of Carolyn E. Bland 1160 Old Canton Pike Cadiz, Kentucky 42211

The name and address of the attorney sending this notice:

William D. Leader, Jr. Leader, Bulso & Nolan, PLC 414 Union Street, Suite 1740 Nashville, Tennessee 37219

Attached hereto is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D).

Pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(E), I also enclose a HIPAA compliant medical authorization permitting you to obtain complete medical records on Carolyn E. Bland from each other provider being sent a notice. If any of those providers does not accept this authorization for any reason, please contact us and we will arrange to execute an authorization acceptable to them that will permit you to obtain complete medical records on Carolyn E. Bland.

Neither this notice nor the medical authorization waives the common law physician patient privilege concerning the care and treatment of Carolyn E. Bland by any doctor who provided medical services for Carolyn E. Bland. We expect that you will not communicate with any person other than your attorney about any doctor's care and treatment of Carolyn E. Bland.

We believe this letter complies with the letter and spirit of Tennessee Code Annotated § 29-26-121. If you believe it is deficient in any way, please let us know and any defect will be promptly cured. If we do not hear from you we will assume that you agree the letter complies with the law.

Very truly yours,
Butleadu

William D. Leader, Jr.

WDL/ Enclosures List of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D)

Re: Carolyn E. Bland and Leon Bland, husband of Carolyn E. Bland

Below is a list of all healthcare providers to whom notice is being given pursuant to Tennessee Code Annotated § 29-26-121(a)(2)(D) of a potential claim for health care liability:

Saint Thomas Outpatient Neurosurgical Center, LLC Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave, Ste 301 Nashville, TN 37203-2023

Saint Thomas Outpatient Neurosurgical Center, LLC Floor 9
4230 Harding Pike
Nashville, TN 37205-2013

Howell Allen Clinic A Professional Corporation Gregory B. Lanford, M.D., registered agent for service of process 2011 Murphy Ave., Ste 301 Nashville, TN 37203-2023

Saint Thomas West Hospital
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas West Hospital 4220 Harding Pike Nashville, TN 37205-2005

Saint Thomas Network
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

Saint Thomas Network 4220 Harding Pike Nashville, TN 37205-2005 Saint Thomas Health
E. Berry Holt III, registered agent for service of process
Ste 800
102 Woodmont Blvd.
Nashville, TN 37205-2221

John Weeks Culclasure, M.D. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

John Weeks Culclasure, M.D. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Debra V. Schamberg, R.N. Nashville, TN 37217

Debra V. Schamberg, R.N. Howell Allen Clinic 2011 Murphy Ave, Suite 301 Nashville, TN 37203

Debra V. Schamberg, R.N. Saint Thomas Outpatient Neurosurgical Center 4230 Harding Pike, Suite 901 Nashville, TN 37205

Patricia G. Beckham Baptist Women's Pavillion 2011 Murphy Ave. Nashville, TN 37203

Patricia G. Beckham The Hospital for Spinal Surgery 2011 Murphy Ave., Suite 400 Nashville, TN 37203

LIMITED AUTHORIZATION TO DISCLOSE MEDICAL INFORMATION OR RECORDS



By signing below, I hereby request and authorize the Health Care Provider identified below to disclose certain information (the "Information") as provided in this Authorization. Information To Be Used Or Disclosed Patient Name: Carolyn E. Bland Patient Identifier: DOB: 1946 Description of Information: Any and all medical information and records, or true and correct copies thereof, in your possession, custody or control, including, but not limited to, medical histories, records, reports, summaries, diagnosis. prognoses, records of treatment and medication ordered and/or given, entries, letters or correspondence to other physicians, electrocardiograms, x-ray films and reports, ultrasounds, diagnostic imaging studies, laboratory data and records, pathological reports, slides and specimens, prescription records, insurance records, bills or statements of account, incident reports, birth certificates, death certificates and all other written or graphic data prepared, kept, made or maintained in your possession, custody or control and summaries of injuries, treatment and prognosis, if requested, that pertain to the Patient. THIS AUTHORIZATION DOES NOT AUTHORIZE VERBAL COMMUNICATIONS WITH THE REFERENCED INDIVIDUAL OR ORGANIZATION. Persons Or Organizations Authorized To Disclose The Information Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic A Professional Health Care Provider. Corporation: Saint Thomas West Hospital; John Weeks Culclasure, M.D.; Debra V. Schamberg, R.N.; Saint Thomas Network; Saint Thomas Health; Patricia G. Beckham I authorize the Health Care Provider(s) and its employees and agents to disclose the Information as provided in this Authorization. A photostatic copy of this Authorization is to be considered as effective as the original. I understand that I am not required to sign this Authorization. The Health Care Provider will not condition treatment, payment, enrollment or eligibility for benefits on whether I sign this Authorization. Persons or Organizations Authorized to Receive the Information Saint Thomas Health or any representative, attorney or investigator from said organization, c/o E. Berry Holt III. Ste 800, 102 Woodmont Blvd., Nashville, TN 37205-2221. Purpose of the Requested Use or Disclosure the resuest of the individual Expiration and Revocation of This Authorization Expiration Date or Event: 7-25-14 I understand that I may revoke this Authorization at any time prior to the expiration date or event, but that my revocation will not have any affect on actions taken by the Health Care Provider, its employees or agents before they received my revocation. Should I desire to revoke this Authorization, I must send written notice to the Health Care Provider at the following address: I understand that I may see and copy the Information if I ask for it. I understand that any Information released may be subject to re-disclosure by the recipient and may no longer be protected by federal or state privacy law or regulations. Signature (Authorized Representative) Date Signature (Patient)

Relationship to Patient

Signature (Witness)



EXHIBIT F

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)	
))	
This Document Relates to:)	MDL No. 1:13-md-2419-FDS
Bland, et al. v. Ameridose, LLC, et al. 1:13-cv-11881-FDS)	

CERTIFICATE OF GOOD FAITH

Medical Malpractice Case

PLAINTIFF'S FORM

A.	In accordan	ice with 7	T.C.A. §	29-26-1	22, I hereby	state the	e following	: (Chec	k item 1	or 2
below	and sign yo	ur name	beneath	the iter	n you have	checked	, verifying	the infe	ormation	you
have c	hecked. Fai	lure to c	heck iten	n 1 or 2	and/or not	signing	item 1 or 2	will m	ake this	case
subject	to dismissal	l with $pr\epsilon$	ejudice.)							

- 1. The Plaintiff or Plaintiff's counsel has consulted with one (1) or more experts who have provided a signed written statement confirming that upon information and belief they:
 - (A) Are competent under § 29-26-115 to express an opinion or opinions in the case; and
 - (B) Believe, based on the information available from the medical records concerning the care and treatment of the Plaintiff for the incident or incidents at issue, that there is a good faith basis to maintain the action consistent with the requirements of § 29-26-115.

Signature of Plaintiff if not represented, or Signature of Plaintiff's Counsel

2.

or

The Plaintiff or Plaintiff's counsel has consulted with one (1) or more experts who have provided a signed written statement confirming that upon information and belief they:

- Are competent under § 29-26-115 to express an opinion or opinions in the case; and
- (B) Believe, based on the information available from the medical records reviewed concerning the care and treatment of the Plaintiff for the incident or incidents at issue and, as appropriate, information from the Plaintiff or others with knowledge of the incident or incidents at issue, that there are facts material to the resolution of the case that cannot be reasonably ascertained from the medical records or information reasonably available to the Plaintiff or Plaintiff's counsel; and that, despite the absence of this information, there is a good faith basis for maintaining the action as to each Defendant consistent with the requirements of § 29-26-115. Refusal of the defendant to release the medical records in a timely fashion or where it is impossible for the Plaintiff to obtain the medical records shall waive the requirement that the expert review the medical records prior to expert certification.

With Afeach.

Signature of Plaintiff fnot represented, or Signature of Plaintiff's Counsel

You MUST complete the information below and sign: В.

I have been found in violation of T.C.A. § 29-26-122 prior times. (Insert number of prior violations by you.)

<u>September 14, 2013</u>